FILED ELECTRONICALLY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/664,004	Confirmation No. 3904
Applicant	:	Burkett et al.	
Filed	:	September 16, 2003	
Art Unit	:	3767	
Examiner	:	Emily Louise Schmidt	
Title	:	DISTALLY TEXTURED POLYMER COATED GUIDE WIRE AND METHOD OF MANUFACTURE	
Docket No.:	:	ACSG-62622 (G3714USO1)	
Customer No.	:	24201	October 14, 2010

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is being filed pursuant to the Notice of Appeal filed on August 20, 2010 from the Final Office Action dated May 28, 2010. This Appeal Brief is being filed within sixty days of the filing of the Notice of Appeal.

INTRODUCTION

The presently claimed invention is directed to an intraluminal guide wire for navigating a body lumen such as a coronary artery. Pursuant to a restriction requirement under 35 U.S.C. § 121, Appellant elected Group I, Species A of Set 1 and Species X of Set 2 in the Response filed on June 17, 2008. Species A relates to

the guide wire shown in FIGS. 5-6, and Species X relates to the guide wire having a constant outer diameter shown in FIG. 19.

The guide wire of the present invention has an elongated core wire having a proximal section that is typically of a constant diameter and a distal section having one or more tapers that gradually have smaller diameters nearing the distal end of the guide wire. At the distal end of the guide wire there is typically a flattened distal end which is surrounded by a helically wound wire coil which is a flexible member used to navigate tortuous coronary arteries without damaging the artery wall. In the embodiment of the invention shown in FIGS. 5 and 6, a number of tactile surface contours are formed on the outer surface of the guide wire, preferably in the distal section of the guide wire. In this embodiment, a number of bumps are disposed along the surface of the guide wire and may be organized in a non-randomized pattern with uniform shapes and sizes or the bumps may be randomized in their locations, sizes and shapes. The bumps have sufficient amplitude or height to change the surface contour of the guide wire, but the generally straight or tapered profile of the wire core remains unchanged. In other words, the bumps change the surface texture of the wire core but do not change and are not independent of the overall profile of the wire core, be it straight, tapered, stepped, curved, or any combination thereof. The guide wire typically is used to navigate within a lumen of a catheter. The bumps on the outer surface of the guide wire reduce the surface contact of the guide wire within the catheter lumen (or a body lumen) and thereby provide a unique tactile feedback to the physician which improves the physician's control and awareness of the guide wire movement through the catheter lumen. A polymer coating extends over the tactile surface contours or bumps and can be a uniform coating or a non-uniform coating over the tactile surface contours or bumps.

The present application, U.S. Serial No. 10/664,004, was filed on September 13, 2003.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is ABBOTT VASCULAR SOLUTION INC., 3200 Lakeside Drive, Santa Clara, CA 95054, which is a division of ABBOTT LABORATORIES, 100 Abbott Park Road, Abbott Park, Illinois 60664-3500. This application was originally assigned by the inventors, DAVID H. BURKETT, KEVIN BRITTON, RYAN GRANDFIELD, PETER J. D'AQUANNI, DAVID WROLSTAD, EDWIN P. MAHIEU, WAYNE E. CORNISH and MARK T. RICHARDSON to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by Assignment executed on September 8, 2003, which was recorded by the U.S. Patent Office on September 16, 2003 beginning at Reel 014508, Frame 0317. ABBOTT VASCULAR SOLUTIONS INC. became the owner of this application when ABBOTT LABORATORIES purchased the ADVANCED CARDIOVASCULAR SYSTEMS, INC. division of GUIDANT CORPORATION.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly effect, or be directly effected by, or have a bearing on the Board's decision on this appeal, it is believed that there are no such appeals or interferences known to the Appellant.

III. STATUS OF CLAIMS

A. Total Number of Claims in the Application

The claims in the application are: Claims 1-3, 6, 7, 10-17, 31. Claims 4, 5, 8, 9 and 18-30 have been withdrawn from consideration.

B. Status of All Claims on Appeal

Claims 1, 3, 6, 10, 11, 13 and 15 have been rejected under 35 U.S.C. § 102(e) as being anticipated by van Sloun et al. (U.S. Publication No. 2004/0010189 A1; the "van Sloun et al. reference").

Claims 2 and 7 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over van Sloun et al. as applied to claim 1, and further in view of McMahon (U.S. Patent No. 6,296,616; the "McMahon patent").

Claim 14 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over van Sloun et al. as applied to claim 1, and further in view of Murayama et al. (U.S. Publication No 2004/0039309 A1; the "Murayama et al. reference").

Claims 1-3, 6, 7, 10, 11 and 14-17 have been rejected under § 103(a) as being unpatentable over Stoltze et al. (U.S. Patent No. 6,033,720; the "Stoltze et al. patent") in view of McMahon, Tezuka (U.S. Patent No. 6,251,085 B1; the "Tezuka patent"), and Sepetka (U.S. Patent No. 5,228,453; the "Sepetka patent").

Claims 12 and 13 have been rejected under § 103(a) as being unpatentable over Stoltze et al., McMahon, Tezuka and Sepetka as applied to claim 1, and further in view of Slaikeu et al. (U.S. Patent No. 5,443,907; the "Slaikeu et al. patent").

Claim 31 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Stoltze et al. in view of McMahon, Tezuka, Sepetka and Slaikeu et al.

C. Claims on Appeal

The claims on appeal are each of pending claims 1-3,6, 7, 10-17 and 31. A copy of the claims being appealed is appended as Exhibit 1.

IV. STATUS OF AMENDMENTS

On May 28, 2010, the Examiner issued a Final Office Action maintaining rejections under 35 U.S.C. §§ 102(e) and 103(a). The finally rejected claims attached to this brief are the subject of this appeal.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent Claim 1

Independent claim 1 is supported in the drawings and specification as follows:

1. (Previously Presented) An intraluminal guide wire (page 9, lines 16-17, FIGS. 5-6, **#42**), comprising:

an elongated wire core (page 9, lines 22-24, FIGS. 5-6, **#64**) having a proximal core section (page 9, lines 20-22, FIGS. 5-6, **#54**) and a distal core section (page 8, lines 12-13, FIGS. 1 and 5-6, **#14**) having a tapered distal end (page 9, lines 19-20, FIGS. 5-6, **#50,52**);

wherein at least a section of the elongated wire core includes at least one of randomized (page 9, lines 24-26, FIGS. 5-6) and non-randomized (page 9, lines 24-26, FIGS. 5-6) tactile surface contours (page 9, lines 22-24, FIGS. 5-6, **#58**);

an uninterrupted polymer coating (page 10, lines 1-2, FIGS. 5-6, **#60**) with a generally constant outside diameter (p. 10, lines 2-7, FIGS. 5-6) adhering to and contiguous with the at least one of randomized and non-randomized tactile surface contours for at least a portion of the elongated wire core including at least a portion (page 10, lines 2-7, FIGS. 5-6) of the tapered distal end and having a surface contour that follows the at least one of randomized and non-randomized tactile surface contours in the elongated wire core; and

a flexible tubular member (page 9, lines 16-18, FIGS. 5-6, **#46**) disposed over the distal core section.

Independent Claim 16

Independent claim 16 is supported in the drawings and specification as follows:

16. (Previously Presented) An intraluminal guide wire (page 9, lines 16-17, FIGS. 5-6, **#42**), comprising:

an elongated core (page 9, lines 22-24, FIGS. 5-6, **#64**) having a proximal core section (page 9, lines 20-22, FIGS. 5-6, **#54**) and a distal core section (page 8, lines 12-13, FIGS. 1 and 5-6, **#14**) including a taper transitioning to a distal end (page 9, lines 19-20, FIGS. 5-6, **#50,52**);

wherein an exterior surface of the distal core section includes randomized tactile surface contours (page 9, lines 22-26, FIGS. 5-6, **#58**) as part of the distal core section itself;

a polymer coating (page 10, lines 1-2, FIGS. 5-6, **#60**) of generally non-uniform thickness (page 10, lines 17-19; page 15, lines 8-11, FIGS. 5-6) adhering without a gap to at least a portion of the distal core section including at least a portion of the tapered transition with a coating profile not following a tapered profile of the elongated core, the polymer coating having tactile surface contours following the randomized surface contours of the exterior surface of the distal core section (page 10, lines 20-23, FIGS. 5-6); and

a flexible tubular member (page 9, lines 16-18, FIGS. 5-6, **#46**) disposed over the distal core section.

Independent Claim 31

Independent claim 31 is supported in the drawings and specification as follows:

31. (Previously Presented) An intraluminal guide wire (page 9, lines 16-17, FIGS. 5-6, **#42**), comprising:

an elongated wire core (page 9, lines 22-24, FIGS. 5-6, **#64**) having a proximal wire core section (page 9, lines 20-22, FIGS. 5-6, **#54**) and a distal wire core section including (page 8, lines 12-13, FIGS. 1 and 5-6, **#14**) a taper transitioning to a distal end (page 9, lines 19-20, FIGS. 5-6, **#50,52**);

wherein an exterior surface of the distal wire core section includes randomized tactile surface contours (page 9, lines 24-26, FIGS. 5-6) that are part of the distal wire core section itself;

a polymer coating (page 10, lines 1-2, FIGS. 5-6, **#60**) of generally non-uniform thickness (page 10, lines 17-19; page 15, lines 8-11, FIGS. 5-6) adhering to and contiguous with at least a portion of the distal core section including at least a portion of the tapered transition with a coating profile not following a tapered profile of the elongated core, the polymer coating having tactile surface contours following the randomized surface contours of the exterior surface of the distal core section (page 10, lines 20-23, FIGS. 5-6);

a flexible tubular member (page 9, lines 16-18, FIGS. 5-6, **#46**) disposed over the distal core section,

wherein:

the surface contours have a surface-to-peak amplitude of about 0.0002 to 0.0020 inch (page 15, lines 20-23);

the flexible tubular member is disposed over the polymer coating (page 8, lines 23-28);

the proximal core section includes a high strength steel and the distal core section includes a nickel-titanium alloy (page 8, lines 14-26; page 9, lines 16-17); and

the polymer coating includes a fluoropolymer (page 15, lines 26-27).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds for appeal are as follows:

GROUND I

Whether claims 1, 3, 6, 10, 11, 13 and 15 were improperly rejected under 35 U.S.C. § 102(e) as being anticipated by the van Sloun et al. reference (Exhibit 2).

GROUND II

Whether claims 1-3, 6, 7, 10, 11 and 14-17 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over the Stoltze et al. patent (Exhibit 3) in view of the McMahon patent (Exhibit 4), the Tezuka patent (Exhibit 5), and the Sepetka patent (Exhibit 6).

GROUND III

Whether claim 31 was improperly rejected as being unpatentable over the Stoltze et al. patent, the McMahon patent, the Tezuka patent, the Sepetka patent and the Slaikeu et al. patent (Exhibit 7).

VII. ARGUMENT

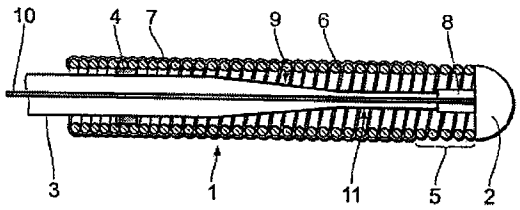
As a preliminary matter, all of the independent claims at issue, namely claims 1, 16 and 31, recite that the elongated wire core has "randomized" tactile surface contours. None of the prior art references cited by the Examiner in the Final Office Action teach or suggest "randomized" tactile surface contours. In fact, the failure to cite any prior art patent having "randomized" tactile surface contours is so evident, that in rejecting independent claims 16 and 31, the Examiner does not refer to a single structural feature in the prior art that teaches or suggests "randomized" tactile surface contours. For this reason alone, all of the pending claims are patentably distinguishable over the prior art.

GROUND I

Rejection of the Claims Based on the van Sloun et al. Reference

Claims 1, 3, 6, 10, 11, 13 and 15 were rejected under 35 U.S.C. § 102(e) as being anticipated by the van Sloun et al. reference. According to the Examiner, van Sloun et al. in FIG. 1 shows an uninterrupted coating 7 with a generally constant outside diameter adhering to and contiguous with the at least one of randomized and non-randomized tactile surface contours. However, FIG. 1 of van Sloun et al. actually shows the coating 7 follow the surface contours of the *coil* 6, while claim 1 recites an "uninterrupted polymer coating with a generally constant outside diameter *adhering to and contiguous with* the at least one of randomized and non-randomized tactile surface contours for at least a portion of the elongated wire *core* ... ." (emphasis added). Thus, because the coating 7 in van Sloun et al. does not adhere to and is not contiguous with the surface contours of the wire "core," this reference does not anticipate claim 1. The coating disclosed in van Sloun et al. is on the surface of the wire "coil 6," not on the elongated wire core.

The Examiner argues at paragraph 2 of the Final Office Action that van Sloun et al. teaches all of the elements of claim 1 of the application and refers to FIG. 1, which shows a tapering region indicated at reference number 9. The Examiner further argues that van Sloun et al. FIG. 1 teaches at least a section of the elongated wire core includes at least one of randomized and non-randomized tactile surface contours, and specifically identifies reference number 6 in FIG. 1 (see FIG. 1 of van Sloun et al. below). There is no teaching in FIG. 1 that the wire coil 6 has a randomized or a non-randomized tactile surface contour.

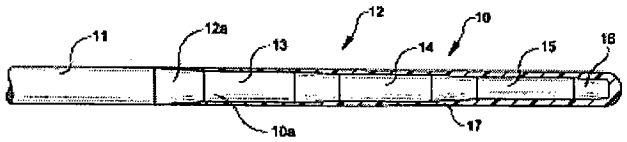


Claim 1 of the present application specifically recites that the elongated core includes at least one of "randomized and non-randomized tactile surface contours." van Sloun et al. does not teach "randomized" tactile surface contours. Assuming *arguendo* that helical coil 6 shown in van Sloun et al. FIG. 1 is a non-randomized tactile surface contour, with uniform and even spacing of the helical coils, it therefore cannot be a "randomized" tactile surface contour as well. Applicant asserts that the helical coil 6 in FIG. 1 of van Sloun et al. cannot be both a "randomized" and non-randomized tactile surface contour.

GROUND II

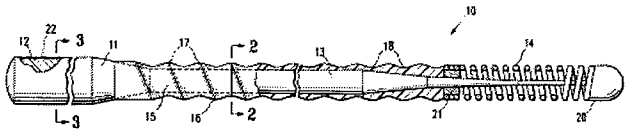
Rejection of the Claims Based on the Stoltze et al., McMahon, Tezuka, and Sepetka Patents

Claims 1-3, 7, 10, 11 and 14-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Stoltze et al. patent in view of McMahon, Tezuka and Sepetka. In the Final Office Action, at paragraph 6, the Examiner acknowledges that Stoltze et al. does not teach the wire core to have tactile surface contours or that the coating follows such contours. As shown in FIG. 3 of Stoltze et al. (below), there are no tactile surface contours.

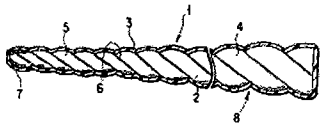


The Examiner relies on FIG. 1 (below) of the McMahon patent to teach a guide wire with a coating with generally constant outside diameter with tactile surface contours

which function to reduce the surface contact and resistance to the movement of the guide wire (referring to FIG. 1, column 3, lines 1-4 of the McMahon patent).



The Examiner relies on FIG. 1 (below) of the Tezuka patent to teach creating surface contours in a guide wire coating by allowing the coating to follow the surface contours of the wire underneath (FIG. 1, column 2, lines 50-57 and column 2, line 63 to column 3, line 5) and to also reduce surface contact for ease of movement.



Appellant contends that it is improper to combine Stoltze et al. and McMahon and Tezuka for several reasons. First, the Examiner is attempting to combine the cited references and alleges, on page 6 of the Final Office Action, that the motivation to combine these references is "for reducing surface contact of the guide wire and reducing resistance to the movement [of the guide wire] ..." and for "ease of movement." Stoltze et al., however, uses a hydrophilic coating 19 to reduce friction between the guide wire assembly and the surrounding vascular structure. (Stoltze et al., column 6, lines 49-53.) On the other hand, McMahon and Tezuka reduce resistance to movement through reducing the surface area of the coating in contact between the guide wire and the body lumen. (McMahon, column 3, lines 1-4 and Tezuka, column 2, line 58 to column 3, line 5.) The Examiner's stated motivation to combine these two references is to improve ease of movement, but this problem was already solved by Stoltze et al. with a hydrophilic coating and already solved by McMahon and Tezuka by reducing surface contact. Hence, the Examiner's stated motivation to combine is not, in fact, present for the three references because each

had already solved the problem. The cited references' disclosures further give no reason to combine or modify their teachings. Appellant contends that there is no motivation or suggestion in Stoltze et al. to combine its teachings with McMahon and Tezuka, or vice versa. Rather, Appellant respectfully notes that the Examiner is improperly using hindsight from Appellant's invention as the motivation to combine these references.

Second, Stoltze et al. makes it clear a number of times in the patent that the outer diameter of the guide wire must remain uniform and constant, which is contrary to adding the contours of the McMahon or Tezuka patents to restructure the Stoltze et al. guide wire. More specifically, in the Stoltze et al. patent, the polymer coating is ground down with a centerless grinding process in order to insure an axially uniform coating thickness (Stoltze et al., column 5, lines 49-58; column 6, lines 17-36). A person having ordinary skill in the art reviewing the Stoltze et al. patent would understand that the objective in coating the guide wire with a polymer and using a centerless grinding process to remove some of the polymer material was for the specific purpose of insuring an axially uniform coating thickness. Contrary to the Examiner's position, a person having ordinary skill in the art would not change the entire structure of the Stoltze et al. guide wire by combining the contoured surface of McMahon or Tezuka to completely change the structure of the Stoltze et al., axially uniform guide wire surface.

This is exactly the type of obviousness rejection that the Supreme Court warned against in *KSR*. The Supreme Court in *KSR*, quoting *In re Kahn*, 441 F.3d. 977, 988, 78 U.S.P.Q. 2d 1329, 1336 (Fed. Cir. 2006) (Exhibit 8), stated that "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. "*KSR International Co.*

v. Teleflex Inc., 550 U.S. 398, 82 U.S.P.Q. 2d, 1385, 1396 (2007) (Exhibit 9). With respect to this particular rejection, there is no "articulated reasoning" to combine the known elements in the manner claimed by Appellant. While the Examiner stated his reason for making the combination at page 6 of the Final Office Action was because the surface contours of McMahon and Tezuka "are beneficial for reducing surface contact of the guide wire and reducing resistance to movement," the hydrophilic coating on the Stoltze et al. guide wire already accomplished these benefits.

> Predictability as discussed in KSR encompasses the expectation that prior art elements are capable of being combined, as well as the expectation that the combination would have worked for its intended purpose. An inference that a claimed combination would not have been obvious is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements. *See* MPEP § 2141 III, Example 4.6, Fed. Reg., Vol. 75, No. 169, at p. 53649 (Exhibit 10), *citing*, *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009) (Exhibit 11).

In this case, the prior art's teaching "undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements." *Id.* Stoltze et al. already has "a hydrophilic coating that is beneficial for reducing surface contact of the guide wire and reducing resistance to movement." (Office Action, page 6.) A person having ordinary skill in the art would not, therefore, be motivated to incorporate the surface contours of McMahon and Tezuka into Stoltze et al. to accomplish the same benefit. Moreover, Stoltze et al. combined with McMahon or Tezuka fails to provide a "predictable result" that would have worked for its intended purpose. Stoltze et al. teaches away from the suggested combination because grinding the polymer coating "results in a uniform coating 17" where the "outer diameter of the plastic coating 17 remains constant" along the guide wire. (Stoltze et

al., column 6, lines 30-36.) Thus, Stoltze et al. teaches away from the proposed combination such that a person of ordinary skill would have been deterred from combining the references as proposed by the Examiner here. See MPEP § 2141 III, at Example 4.6.

Third, the McMahon patent should not be combined with the Stoltze et al. patent because McMahon fails to teach or suggest "an uninterrupted polymer coating with a generally constant outside diameter adhering to and contiguous with the at least one of randomized and non-randomized tactile surface contours... ." Importantly, as has been argued repeatedly in this prosecution, the polymer coating of McMahon in fact forms the surface contours, it does not coat the already formed randomized and non-randomized tactile surface contours as recited in claim 1.

Fourth, with reference to independent claim 16, none of the cited references teach or suggest "randomized" tactile surface contours as part of the distal core section. Further, none of the cited references teach or suggest a "polymer coating having tactile surface contours following the randomized surface contours of the exterior surface of the distal core section" as recited in claim 16. The Examiner has admitted that Stoltze et al. "does not teach the wire core to have tactile surface contours or that the coating follows such contours." Further, as repeatedly pointed out during this prosecution, the McMahon patent teaches a polymer coating that forms the surface contours, it is not a polymer coating that follows "randomized surface contours" that is on the exterior surface of the distal core section as recited in claim 16. Likewise, the Tezuka patent also fails to teach or suggest "randomized" tactile surface contours as part of the distal core section. In view of all of the foregoing, it is respectfully urged that independent claims 1 and 16, and the claims that depend therefrom, are patentably distinguishable over the prior art.

GROUND III

Claim 31 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stoltze et al. in view of McMahon, Tezuka, Sepetka, and Slaikeu et al. Independent claim 31, like independent claim 16, recites in pertinent part that the distal wire core section includes "randomized" tactile surface contours that are part of the distal wire core section. Further, independent claim 31 recites "a polymer coating of generally non-uniform thickness adhering to and contiguous with at least a portion of the distal core section" and "a polymer coating having tactile surface contours following the randomized surface contours of the exterior surface of the distal core section." None of the prior art references alone or in combination teach or suggest the recited claim elements. More specifically, Appellant incorporates all of the arguments set forth *supra* with respect to the rejections in Ground II.

In addition, the Sepetka patent was cited by the Examiner to show an increase in radiopacity and to improve torque and the Slaikeu et al. patent was cited by the Examiner for teaching a polymer coating to provide low friction and a flexible member that provides radiopacity. Neither Sepetka or Slaikeu et al. teach or suggest structure that overcomes the shortcomings of the main reference Stoltze et al., or the other references to McMahon and Tezuka. More specifically, none of the cited references teach "an exterior surface of the distal wire core section includes **randomized** tactile surface contours that are part of the distal wire core section itself." (Emphasis added.) Similarly, none of the cited references teach the polymer coating having tactile surface contours following the randomized surface contours of the exterior surface of the distal core section. In view of all of the foregoing, it is respectfully urged that claim 31 is patentably distinguishable over the cited art.

IV. CLAIM APPENDIX

See Exhibit 1.

V. EVIDENCE APPENDIX

None.

VI. RELATED PROCEEDINGS APPENDIX

NONE

VII. CONCLUSION

Appellant respectfully requests that the rejections under 35 U.S.C. §§ 102(e) and 103(a) be withdrawn.

The fee of $540.00 for the filing of Appellant's Appeal Brief is being paid concurrently herewith. The Commissioner is hereby authorized, however, to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LLP

/John S. Nagy/
John S. Nagy, Reg. No. 30,664

JSN:jeb

LIST OF EXHIBITS

EXHIBIT	DESCRIPTION
1	Appealed Claims
2	U.S. Publication No. 2004/0010189 A1 to van Sloun et al.
3	U.S. Patent No. 6,033,720 to Stoltze et al.
4	U.S. Patent No. 6,296,616 to McMahon
5	U.S. Patent No. 6,251,085 to Tezuka
6	U.S. Patent No. 5,228,453 to Sepetka
7	U.S. Patent No. 5,443,907 to Slaikeu et al.
8	In re Kahn, 78 U.S.P.Q. 2d 1329 (Fed. Cir. 2006)
9	*KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 U.S.P.Q. 2d 1385 (2007)
10	Fed. Reg., Vol. 75, No. 169, pp. 53643-53660
11	*DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009)

EXHIBIT 1

CLAIMS

1. (Previously Presented) An intraluminal guide wire, comprising:

an elongated wire core having a proximal core section and a distal core section having a tapered distal end;

wherein at least a section of the elongated wire core includes at least one of randomized and non-randomized tactile surface contours;

an uninterrupted polymer coating with a generally constant outside diameter adhering to and contiguous with the at least one of randomized and non-randomized tactile surface contours for at least a portion of the elongated wire core including at least a portion of the tapered distal end and having a surface contour that follows the at least one of randomized and non-randomized tactile surface contours in the elongated wire core; and

a flexible tubular member disposed over the distal core section.

2. (Original) The intraluminal guide wire of claim 1, wherein the surface contours have a surface-to-peak amplitude of about 0.0002 to 0.002 inch.

3. (Original) The intraluminal guide wire of claim 1, wherein tactile surface contours include at least a bump.

4. (Withdrawn) The intraluminal guide wire of claim 1, wherein tactile surface contours include at least a divot.

5. (Withdrawn) The intraluminal guide wire of claim 1, wherein tactile surface contours include at least a helical pattern.

6. (Original) The intraluminal guide wire of claim 1, wherein tactile surface contours include at least a rib.

7. (Original) The intraluminal guide wire of claim 1, wherein tactile surface contours includes a plurality of ribs spaced about 0.05 cm to 2 cm apart.

8. (Withdrawn) The intraluminal guide wire of claim 1, wherein tactile surface contours include at least an undulation.

9. (Withdrawn) The intraluminal guide wire of claim 1, wherein tactile surface contours include at least a longitudinal groove.

10. (Original) The intraluminal guide wire of claim 1, wherein tactile surface contours include ridges and dips.

11. (Original) The intraluminal guide wire of claim 1, wherein tactile surface contours include at least a circumferential groove.

12. (Original) The intraluminal guide wire of claim 1, wherein the flexible tubular member is disposed over the polymer coating.

13. (Original) The intraluminal guide wire of claim 1, wherein the polymer coating is disposed over the flexible tubular member.

14. (Original) The intraluminal guide wire of claim 1, wherein the proximal core section includes a high strength steel and the distal core section includes a nickel-titanium alloy.

15. (Original) The intraluminal guide wire of claim 1, wherein the polymer coating includes a fluoropolymer.

16. (Previously Presented) An intraluminal guide wire, comprising:

an elongated core having a proximal core section and a distal core section including a taper transitioning to a distal end;

wherein an exterior surface of the distal core section includes randomized tactile surface contours as part of the distal core section itself;

a polymer coating of generally non-uniform thickness adhering without a gap to at least a portion of the distal core section including at least a portion of the tapered transition with a coating profile not following a tapered profile of the elongated core, the polymer coating having tactile surface contours following the randomized surface contours of the exterior surface of the distal core section; and

a flexible tubular member disposed over the distal core section.

17. (Original) The intraluminal guide wire of claim 16, wherein the tactile surface contours includes a rib.

18. (Withdrawn) The intraluminal guide wire of claim 16, wherein the tactile surface contours includes a helical pattern.

19. (Withdrawn) The intraluminal guide wire of claim 16, wherein the tactile surface contours includes a longitudinal groove.

20. (Withdrawn) A method for providing an intraluminal guide wire, comprising:

providing an elongated core having a proximal core section and a distal core section having a smooth exterior surface;

tapering a profile of the elongated core to transition into a distal end;

heating and extruding a polymer through a die to adhere to at least a portion of the elongated core to create a polymer coating; and

imparting into the polymer coating at least one of randomized and non-randomized tactile surface contours that are formed independently from the profile of the elongated core.

21. (Withdrawn) The method of claim 20, wherein imparting into the polymer coating includes localized heating of the polymer coating.

22. (Withdrawn) The method of claim 21, wherein localized heating includes laser heating.

23. (Withdrawn) The method of claim 21, wherein localized heating includes laser heating aimed at right angle to the elongated core while advancing and rotating elongated core past the laser.

24. (Withdrawn) The method of claim 21, wherein localized heating includes translating the polymer coating past a heat source emitting heat in cycles.

25. (Withdrawn) The method of claim 20, wherein imparting into the polymer coating includes changing an advancement speed of the elongated core through the die.

26. (Withdrawn) The method of claim 20, wherein imparting into the polymer coating include applying impulse force to polymer.

27. (Withdrawn) The method of claim 20, wherein imparting into the polymer coating at least one of randomized and non-randomized tactile surface contours includes providing bumps in at least a portion of the elongated core.

28. (Withdrawn) The method of claim 27, wherein providing bumps in at least a portion of the elongated core includes drawing the elongated core through a die.

29. (Withdrawn) The method of claim 20, wherein imparting into the polymer coating at least one of randomized and non-randomized tactile surface contours includes particle blasting the elongated core.

30. (Withdrawn) The method of claim 20, wherein the polymer includes a fluoropolymer.

31. (Previously Presented) An intraluminal guide wire, comprising:

an elongated wire core having a proximal wire core section and a distal wire core section including a taper transitioning to a distal end;

wherein an exterior surface of the distal wire core section includes randomized tactile surface contours that are part of the distal wire core section itself;

a polymer coating of generally non-uniform thickness adhering to and contiguous with at least a portion of the distal core section including at least a portion of the tapered transition with a coating profile not following a tapered profile of the elongated core, the polymer coating having tactile surface contours following the randomized surface contours of the exterior surface of the distal core section;

a flexible tubular member disposed over the distal core section,

wherein:

the surface contours have a surface-to-peak amplitude of about 0.0002 to 0.0020 inch;

the flexible tubular member is disposed over the polymer coating;

the proximal core section includes a high strength steel and the distal core section includes a nickel-titanium alloy; and

the polymer coating includes a fluoropolymer.

EXHIBIT 2

US 20040010189A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2004/0010189 A1

van Sloun et al. (43) Pub. Date: Jan. 15, 2004

(54) GUIDE WIRE

(75) Inventors: **Math J.J. van Sloun**, Berg aan de Maas (NL); **Dick Vos**, Dalfsen (NL); **Cornelius Carolus de Cock**, Haarlem (NL)

Correspondence Address:
HAHN LOESER & PARKS, LLP
TWIN OAKS ESTATE
1225 W. MARKET STREET
AKRON, OH 44313 (US)

(73) Assignee: **Biotronik Mess-und Therapiegeraete GmbH & Co. Ingenieurbuero Berlin**

(21) Appl. No.: **10/334,046**

(22) Filed: **Dec. 30, 2002**

(30) **Foreign Application Priority Data**

Jul. 2, 2001 (DE)..... 101 32 332.1

Publication Classification

(51) **Int. Cl.**[7] **A61B 5/04**

(52) **U.S. Cl.** **600/374**; 607/122; 600/585

(57) **ABSTRACT**

A guide wire (1) is provided which can be introduced intravascularly and which is used for implanting a catheter in a heart with an electrode (2, 5). In that arrangement, the guide wire (1) is first used as a temporary electrode (2, 5) for stimulating, defibrillating and/or sensing the heart in order to determine the optimum implantation position for the catheter to be introduced. When that optimum position is determined, the guide wire (1) is left at that position and the catheter is introduced along the guide wire (1) to the ascertained position and implanted. Once the catheter is implanted, the guide wire (1) is removed.

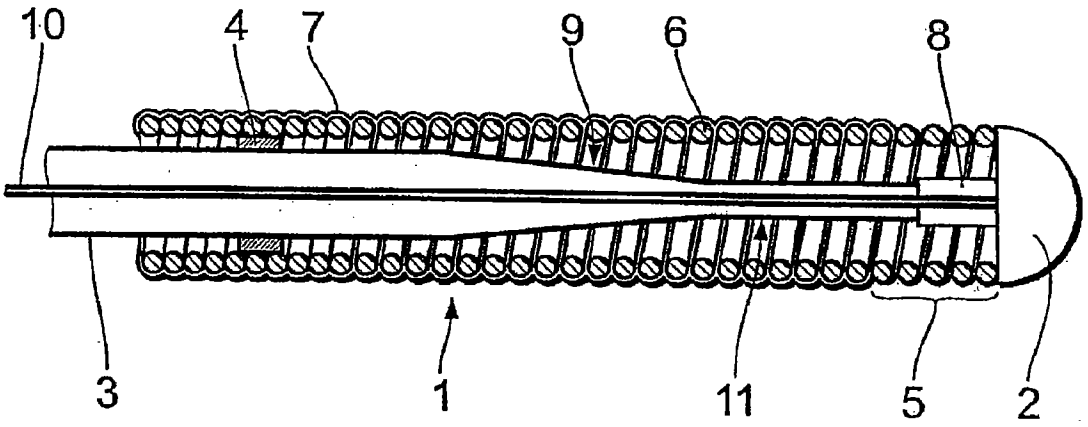


EXHIBIT 2

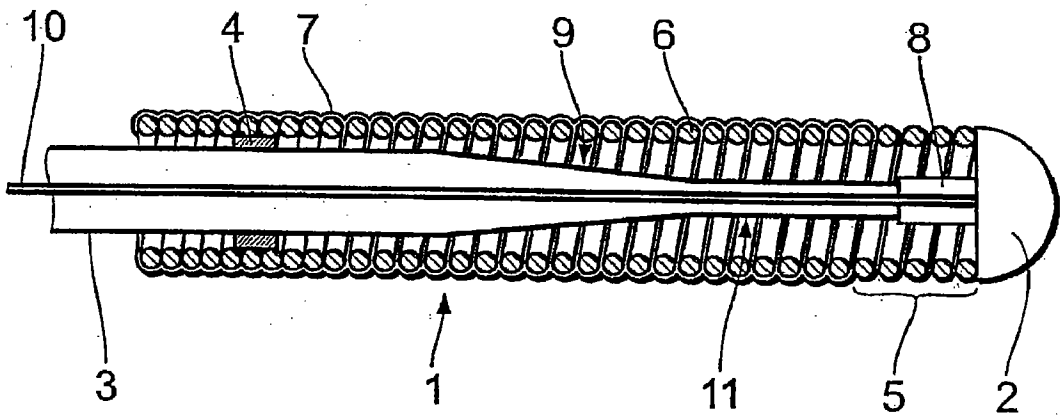


Fig. 1

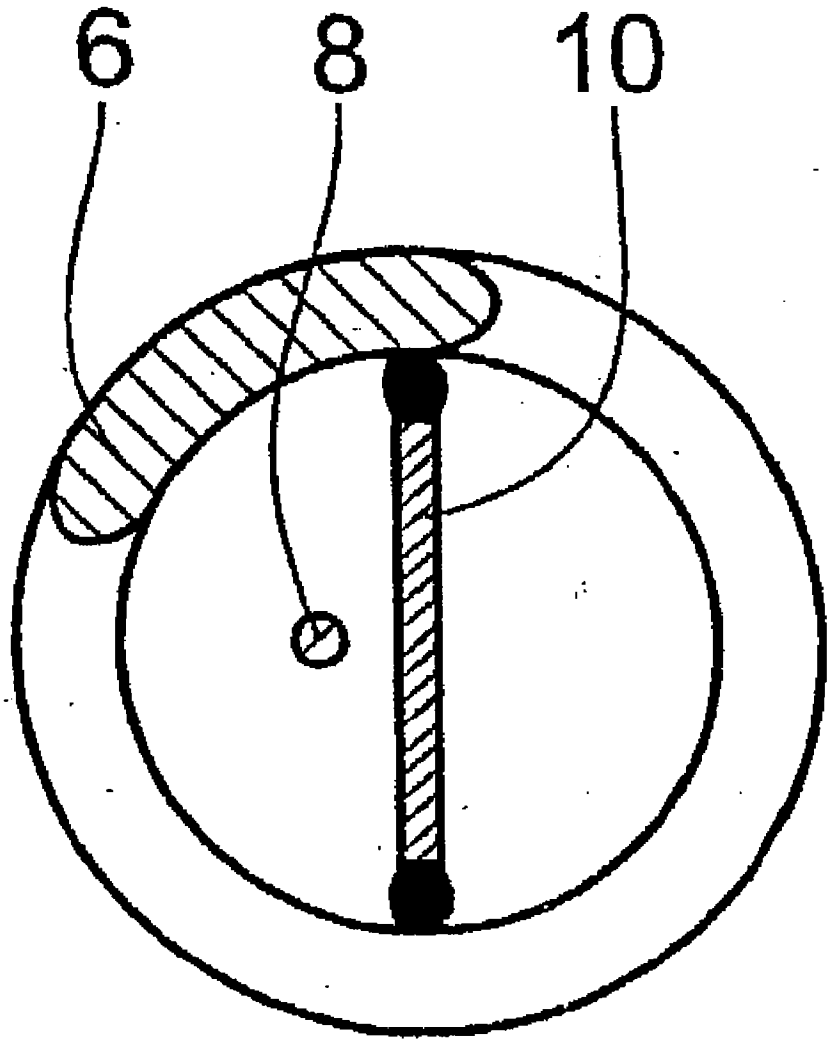


Fig. 2

GUIDE WIRE

[0001] The present invention concerns a controllable guide wire, in particular for use during implantation of catheters in a heart, wherein the guide wire is adapted to be introduced intravascularly so that a catheter can then be introduced for implantation purposes along the guide wire, and wherein the guide wire is adapted to be removed again after implantation of the catheter.

BACKGROUND OF THE ART

[0002] In the case of patients with pronounced heart failure, stimulation of the heart can prove to be advantageous. However, just in relation to a small group (with a long PR-interval), stimulation in the right ventricle resulted in significant improvements. Other stimulation arrangements were investigated for modification of the left ventricular function of the heart. It emerged that optimum stimulation of the heart in regard to the hemodynamic state of the heart appears to be different for each patient.

[0003] Therefore, to establish an optimum stimulation arrangement for the patient, it is absolutely necessary for the heart of the patient to be firstly investigated with regard to optimum therapy and an optimum arrangement of the respective electrodes, in regard to the desired hemodynamic values.

[0004] U.S. Pat. No. 5,549,109, to Samson, discloses a catheter and a guide wire for reproducing the coronary electrical activity in the coronary arteries and/or veins, wherein both the catheter and also the guide wire have electrodes. The guide wire and the catheter can be introduced from an external location, such as, for example, the femoral artery or vein, into the cardiac arteries or veins. The guide wire and the catheter are placed there in such a way that the local cardiac electrical activity in the cardiac muscle wall is measured and monitored. A complete image of the electrical activity of the heart can be formed by the variation in the measurement locations in the coronary vascular system.

[0005] When a complete image of the electrical activity of the heart has been produced the catheter together with the guide wire is removed from the patient again so that an electrical therapy device can be permanently implanted with a suitable catheter for stimulation and/or defibrillation of the heart. In that respect, the operation of introducing the catheter to the desired position is found to be highly complex as inaccurate placement has an adverse effect on the stimulation and defibrillation properties. In that respect it is in particular very difficult to precisely find the optimum placement for the catheter again.

[0006] Therefore the object of the invention is to provide a guide wire with which the placement of a catheter to be introduced can be improved.

SUMMARY OF THE INVENTION

[0007] That object is attained by a guide wire of the kind set forth in the opening part of this specification, with the characterizing features of accompanying claim 1.

[0008] In that respect the invention is based on the idea of providing a guide wire which can be introduced intravascularly and which is used for the implantation of a catheter into a heart with an electrode. In that case the guide wire is firstly used as a temporary electrode for stimulation, defibrillation and/or sensing of the heart in order to determine the optimum implantation position for the catheter to be introduced. When that optimum position is determined the guide wire is left at that position and the catheter is introduced along the guide wire to the ascertained position and implanted. As soon as the catheter has been implanted the guide wire is removed again.

[0009] The advantages that the invention entails are that the optimum implantation position for the catheter to be implanted is ascertained by a guide wire with the electrode, and that the guide wire is left at that position and the catheter is introduced along the guide wire to that position. This ensures that the catheter is implanted at the precise ascertained position, thereby achieving optimum stimulation and defibrillation properties.

[0010] In a preferred configuration of the invention, the guide wire is provided with a single electrode which is preferably disposed at the distal end of the guide wire.

[0011] In a further embodiment of the invention, X-ray markers are provided on the guide wire. Those X-ray markers serve to make the, ascertained implantation position for the catheter to be implanted visible even outside the body so that the doctor carrying out the implantation operation can monitor the implantation procedure and finds the ascertained implantation position again more easily.

[0012] In still a further embodiment of the invention, a mechanical or a magnetic abutment is mounted to the distal end of the guide wire so that it can indicate the end of the guide wire and the doctor carrying out the implantation operation does not push the catheter beyond the distal end of the guide wire and thus miss the optimum implantation position.

[0013] In a further preferred embodiment of the invention, an optical marking is provided at the proximal end of the guide wire so that it is possible to perceive when the catheter to be introduced has been advanced to the ascertained implantation position. That optical marking also serves to provide that the catheter is not pushed beyond the distal end of the guide wire and thus misses the optimum position.

[0014] In a further particularly preferred embodiment of the invention, the guide wire is of a diameter of between 0.4 and 0.8 mm. That diameter range ensures that the guide wire can move to all desired positions in the cardiovascular system.

[0015] Further configurations according to the invention are the subject matter of the appendant claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Better understanding of the present invention will be obtained from reference to the accompanying drawings, in which identical parts are identified with identical reference numbers and in which:

[0017] **FIG. 1** shows a view in section of a guide wire, and

[0018] **FIG. 2** shows a cross-section at the distal end of the guide wire in **FIG. 1**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0019] **FIG. 1** shows a sectional view of a guide wire **1**. The guide wire **1** has a helical coil **6** that extends as far as

the distal end of a shank **3**. At its distal end the shank **3** is connected to a rounded tip **2** and also by way of a solder join **4** to the coil **6**.

[**0020**] The shank **3** in wire form is coated with a polytetrafluoroethylene coating, such as TEFLON, and is provided distally in relation to a tapering region **9** with a region **11** of reduced width and a wider region **8** at the distal end of the shank which is of a pressed-flat configuration and joined to the rounded tip **2**. By virtue of the shank **3** being pressed flat at its distal end, that is to say in the region **8**, the transmission of torsion is increased and at the same time the risk of fatigue is reduced.

[**0021**] At its outside surface the guide wire **1** has substantially—with the exception of the portion **5**—a TEFLON coating **7** that is used as insulation. That coating also serves to reduce the friction of the guide wire. The non-insulated portion **5** is used as an electrode, the electrical contacting of which is effected by way of the coil **6**.

[**0022**] The turns of the coil **6** are slightly opened at the distal end thereof, that is to say in the region of the portion **5**, in order to increase the flexibility of the distal end of the guide wire **1**.

[**0023**] The guide wire **1** also has a control wire **10** that is fixed at its distal end to the rounded tip **2** and which extends as far as the proximal end of the guide wire **1**.

[**0024**] **FIG. 2** shows a cross-section through the guide wire **1** in its distal region. The flat-pressed distal end **8** of the shank **3** and the distal end of the control wire **10** are in this case fixed in the rounded tip **2**. The coil **6** is arranged around the shank **3** and the control wire **10**.

[**0025**] When the control wire **10** is actuated or pulled in the proximal direction the distal end of the guide wire **1** experiences a flexing effect in accordance with the extent of actuation. The control wire **10** is suitably actuated for maneuvering in arteries and veins so that the distal end of the guide wire **1** flexes and the guide wire can thus be advanced around a bend or into a further artery or vein. As the guide wire **1** can only be flexed in one direction by means of the control wire **10** it is necessary for the entire guide wire to be rotated if the distal end of the guide wire **1** is to be flexed in a different direction. That is effected by rotating the shank **3** which is connected to the coil **6** by way of the solder join **4** and to the rounded tip **2**.

[**0026**] As described hereinbefore the guide wire **1** is maneuvered through arteries and veins in order to pass into the atrium or the ventricle. When the distal end of the guide wire **1** has reached the desired location in the atrium or ventricle the non-insulated portion **5** is used as a monopolar electrode. In that case the monopolar electrode **5** is used as a temporary electrode in order to sense, stimulate and/or defibrillate the tissue therearound. The results of sensing, stimulation and defibrillation at that position are recorded. That recording procedure is carried out for a plurality of positions in the atrium and in the ventricle in order to find the optimum position for a catheter to be implanted for sensing, stimulation or defibrillation purposes.

[**0027**] When the optimum position is found the distal end of the guide wire is left at that position and the catheter to be introduced is introduced along the guide wire **1** to the distal end of the guide wire **1** ("over the wire" or "mono-rail"). As soon as the catheter has been introduced and implanted the guide wire **1** is removed again.

[**0028**] The guide wire **1** thus only serves to find an optimum implantation position and to introduce a catheter to be implanted, to the optimum implantation position found. The guide wire **1** is not intended for permanent implantation.

[**0029**] The guide wire can be positioned for example in the region of the coronary sinus in order to stimulate the left ventricle.

[**0030**] As an alternative to using the non-insulated portion **5** as a monopolar electrode it is also possible to use the rounded tip **2** of the guide wire **1** as an electrode, preferably as a tip electrode. For that purpose the portion **5** is provided with an insulating material and the insulation is removed around the rounded tip **2** of the guide wire **1**. In that case the rounded tip **2** can be electrically contacted by way of the shank **3**.

[**0031**] The diameter of the guide wire **1** is in the diameter range of between 0.4 and 0.8 mm.

[**0032**] Provided at the distal end of the guide wire **1** is an X-ray marker, preferably comprising gold. As an alternative thereto, the rounded tip **2** can be made from gold and can thus serve as an X-ray marker. The optimum implantation position ascertained by the guide wire **1** as a temporary electrode can be rendered visible by means of such an X-ray marker in order then to be able to move exactly to that position with an electrode catheter which is also provided with an X-ray marker.

[**0033**] As an alternative thereto, it is possible to envisage a mechanical marking in the form of an abutment at the distal end of the guide wire **1**, which provides that, upon being inserted to the optimum implantation position ascertained, the catheter is not unintentionally introduced beyond the distal end of the guide wire **1** and thus misses the optimum implantation position. In that case however the abutment is not to be designed in such a way that it is insurmountable as otherwise the guide wire would no longer be removable after the implantation operation. As an alternative to the mechanical abutment a magnetically perceptible abutment would also be possible. A magnetic abutment of that kind could be implemented for example by using magnets at the distal end of the guide wire and at the distal end of the catheter to be implanted.

[**0034**] A further alternative way of preventing the catheter being introduced beyond the distal end of the guide wire **1** represents an optical marking on the guide wire and/or the catheter respectively in the proximal region thereof, that is to say outside the body of the patient. By reference to an optical marking of that kind it is possible for the operator of the guide wire **1** and the catheter to recognize when the distal end of the catheter to be introduced has reached the distal end of the guide wire so that the catheter to be introduced is thus at the desired implantation position and can be implanted.

What is claimed is:

1. A controllable guide wire, especially for use in implanting a catheter in a heart, wherein the guide wire has a proximal and a distal end and is adapted to be introduced intravascularly so that the catheter may be introduced for

implantation therealong and wherein the guide wire is adapted to be removed after implanting the catheter, comprising:

at least one electrode fixed to the guide wire, said at least one electrode being adapted, when the guide wire is introduced, to stimulate, defibrillate and/or sense adjoining tissue in order to determine an optimum intravascular implantation location for the cathode to be implanted,

wherein the guide wire is adapted to introduce the catheter to be implanted along the guide wire to the implantation location determined by said at least one electrode.

2. The guide wire of claim 1, comprising a single electrode.

3. The guide wire of claim 2, wherein the electrode is at the distal end of the guide wire.

4. The guide wire of claim 1, further comprising:

at least one X-ray marker on the guide wire, the marker being adapted to make the ascertained implantation position visible outside the body.

5. The guide wire of claim 2, further comprising:

at least one X-ray marker on the guide wire, the marker being adapted to make the ascertained implantation position visible outside the body.

6. The guide wire of claim 3, further comprising:

at least one X-ray marker on the guide wire, the marker being adapted to make the ascertained implantation position visible outside the body.

7. The guide wire of claim 1, further comprising:

a mechanical abutment at the distal end of the guide wire, the abutment being adapted to indicate the distal end of the guide wire.

8. The guide wire of claim 2, further comprising:

a mechanical abutment at the distal end of the guide wire, the abutment being adapted to indicate the distal end of the guide wire.

9. The guide wire of claim 5, further comprising:

a mechanical abutment at the distal end of the guide wire, the abutment being adapted to indicate the distal end of the guide wire.

10. The guide wire of claim 1, further comprising:

a magnetic, perceptible abutment at the distal end of the guide wire, the abutment being adapted to indicate the distal end of the guide wire.

11. The guide wire of claim 2, further comprising:

a magnetic, perceptible abutment at the distal end of the guide wire, the abutment being adapted to indicate the distal end of the guide wire.

12. The guide wire of claim 9, further comprising:

a magnetic, perceptible abutment at the distal end of the guide wire, the abutment being adapted to indicate the distal end of the guide wire.

13. The guide wire of claim 1, further comprising:

an optical marking at the proximal extracorporal end of the guide wire, the optical marking being adapted be visible when the catheter to be introduced has been advanced as far as the ascertained implantation location.

14. The guide wire of claim 2, further comprising:

an optical marking at the proximal extracorporal end of the guide wire, the optical marking being adapted be visible when the catheter to be introduced has been advanced as far as the ascertained implantation location.

15. The guide wire of claim 4, further comprising:

an optical marking at the proximal extracorporal end of the guide wire, the optical marking being adapted be visible when the catheter to be introduced has been advanced as far as the ascertained implantation location.

16. The guide wire of claim 7, further comprising:

an optical marking at the proximal extracorporal end of the guide wire, the optical marking being adapted be visible when the catheter to be introduced has been advanced as far as the ascertained implantation location.

17. The guide wire of claim 10, further comprising:

an optical marking at the proximal extracorporal end of the guide wire, the optical marking being adapted be visible when the catheter to be introduced has been advanced as far as the ascertained implantation location.

18. The guide wire of claim 12, further comprising:

an optical marking at the proximal extracorporal end of the guide wire, the optical marking being adapted be visible when the catheter to be introduced has been advanced as far as the ascertained implantation location.

19. The guide wire of claim 1, wherein the guide wire has a diameter between 0.4 and 0.8 mm.

20. The guide wire of claim 18, wherein the guide wire has a diameter between 0.4 and 0.8 mm.

21. The guide wire of claim 1, wherein a wire coil provides the electrical feed for said at least one electrode of the guide wire.

22. The guide wire of claim 2, wherein a wire coil provides the electrical feed for the single electrode of the guide wire.

23. The guide wire of claim 20, wherein a wire coil provides the electrical feed for the single electrode of the guide wire.

24. The guide wire of claim 1, wherein a shank provides the electrical feed for the said at least one electrode of the guide wire.

25. The guide wire of claim 2, wherein a shank provides the electrical feed for the single electrode of the guide wire.

26. The guide wire of claim 20, wherein a shank provides the electrical feed for the said at least one electrode of the guide wire.

* * * * *

EXHIBIT 3

US006033720A

United States Patent [19]

Stoltze et al.

[11] Patent Number: 6,033,720

[45] Date of Patent: Mar. 7, 2000

[54] **GUIDEWIRE HAVING A COATED TIP**

[75] Inventors: **Jacob Stoltze**, Copenhagen; **Jorgen Kamstrup-Larsen**, Allerod, both of Denmark

[73] Assignee: **Meadox Medicals, Inc.**, Oakland, N.J.

[21] Appl. No.: **09/271,518**

[22] Filed: **Mar. 18, 1999**

Related U.S. Application Data

[62] Division of application No. 08/496,956, Jun. 30, 1995.

[51] **Int. Cl.**[7] **B05D 3/12**; B05D 1/38

[52] **U.S. Cl.** **427/2.3**; 427/2.12; 427/160; 427/358; 427/359; 427/365; 427/205

[58] **Field of Search** 427/118, 119, 427/120, 2.12, 2.1, 278, 287, 358, 359, 365, 2.28, 160, 277, 203, 205; 600/585

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,049,601	9/1977	Anderson	260/24
4,642,267	2/1987	Creasy et al.	428/413
4,841,976	6/1989	Packard et al.	128/657
4,876,126	10/1989	Takemura et al.	428/35.7
4,884,579	12/1989	Engelson	128/772
4,925,445	5/1990	Sakamoto et al.	604/95
5,035,694	7/1991	Kasprzyk et al.	606/27
5,040,543	8/1991	Baders et al.	128/772
5,061,424	10/1991	Karimi et al.	264/171
5,095,915	3/1992	Engelson	128/772
5,129,890	7/1992	Bates et al.	604/281
5,201,754	4/1993	Crittenden et al.	606/194
5,213,111	5/1993	Cook et al.	128/772
5,217,026	6/1993	Stoy et al.	128/772
5,275,173	1/1994	Samson et al.	128/772
5,304,140	4/1994	Kugo et al.	604/281
5,312,356	5/1994	Engelson et al.	604/164
5,385,152	1/1995	Abele et al.	128/772
5,401,257	3/1995	Chevalier, Jr. et al.	604/265
5,402,799	4/1995	Colon et al.	128/772
5,403,292	4/1995	Ju	604/282
5,443,907	8/1995	Slaikeu et al.	428/375
5,452,726	9/1995	Burmeister et al.	600/585
5,756,144	5/1998	Wolff et al.	427/2.1
5,897,819	4/1999	Miyata et al.	427/421

FOREIGN PATENT DOCUMENTS

93094 A1	11/1983	European Pat. Off. .
389632 A1	10/1990	European Pat. Off. .
395098 A1	10/1990	European Pat. Off. .
407965 A1	1/1991	European Pat. Off. .
2214169	10/1973	Germany .
1435797	5/1976	United Kingdom .
2212169	7/1989	United Kingdom .
WO 91/19756	12/1991	WIPO .
WO 93/08862	5/1993	WIPO .

OTHER PUBLICATIONS

Norton Bonded Abrasives Training Course, *Centerless Grinding*, (date unknown), p. 1–27.

Primary Examiner—Diana Dudash
Attorney, Agent, or Firm—Hoffmann & Baron, LLP

[57] **ABSTRACT**

A guidewire includes a shaft portion and a tip portion with the tip portion having a plastic tubular coating thereover. The shaft portion of the guidewire has a given diameter and the tip portion has a diameter which decreases towards a distal end thereof. A tubular plastic coating is placed on at least the tip portion of the guidewire. The outer diameter of the coating on the tip portion exceeds the diameter of the shaft portion. The diameter of the plastic coating is reduced so as to be no greater than the diameter of the shaft portion. A hydrophilic coating may be applied over the shaft and the tip portion of the guidewire.

25 Claims, 3 Drawing Sheets

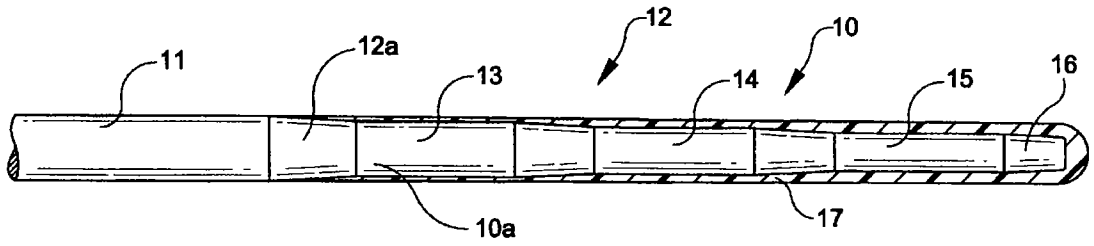


EXHIBIT 3

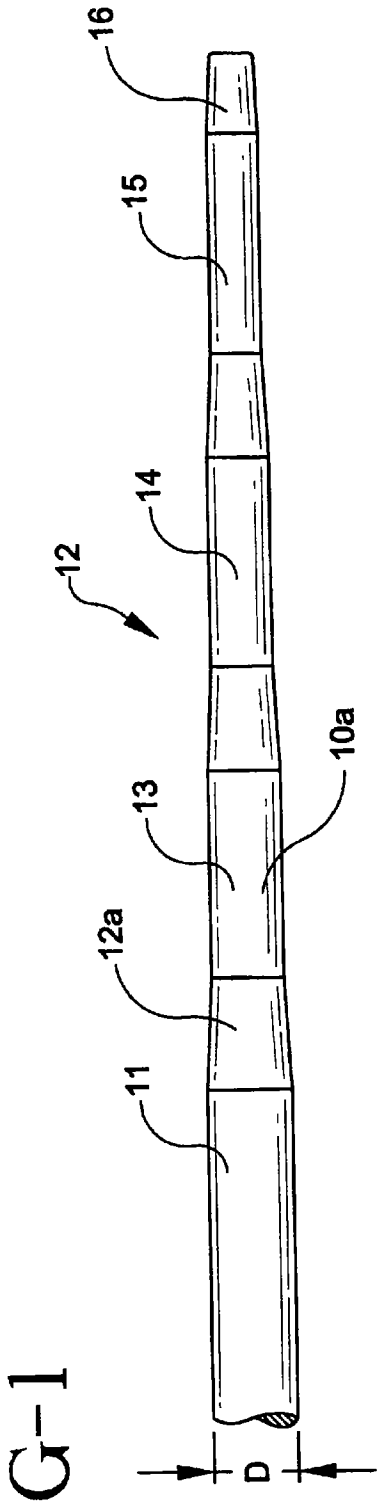


FIG-1

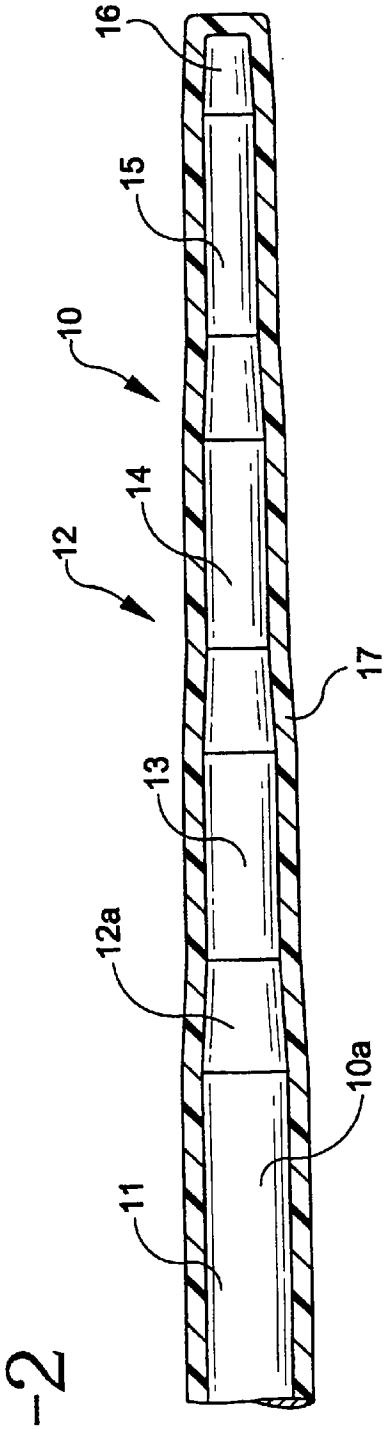


FIG-2

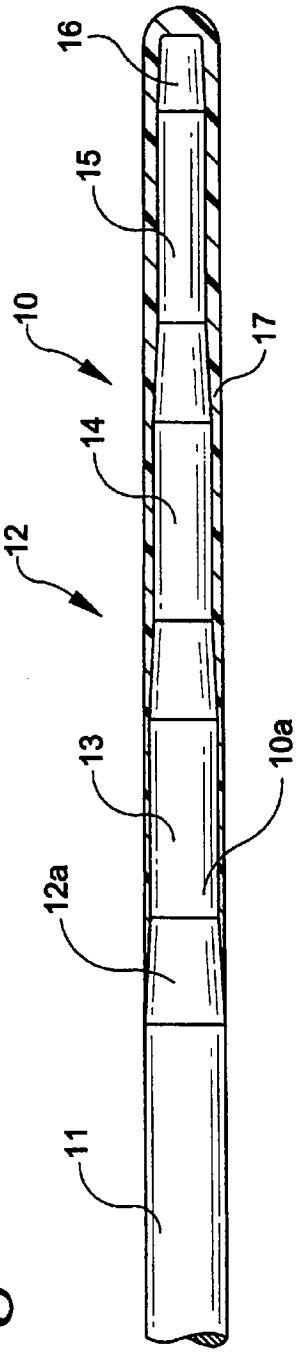

16
15
10
17
14
12
13
10a
12a
11

FIG-3

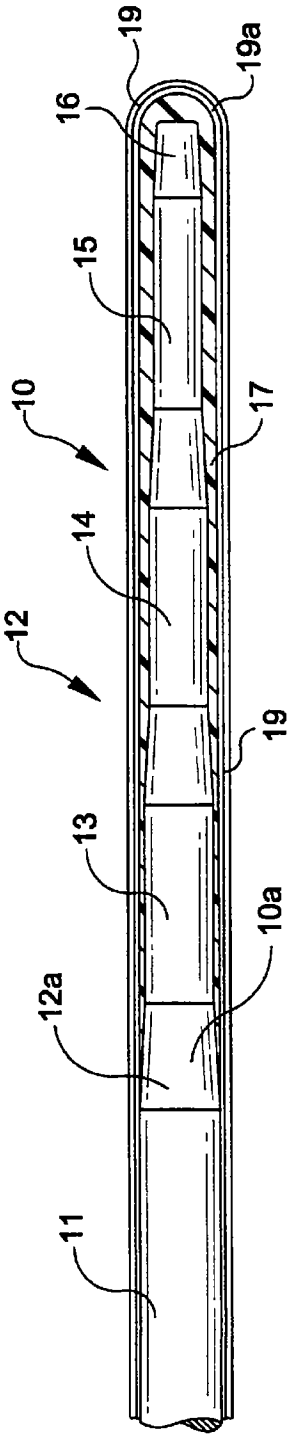

19
19a
16
15
10
17
14
12
19
13
10a
12a
11

FIG-4

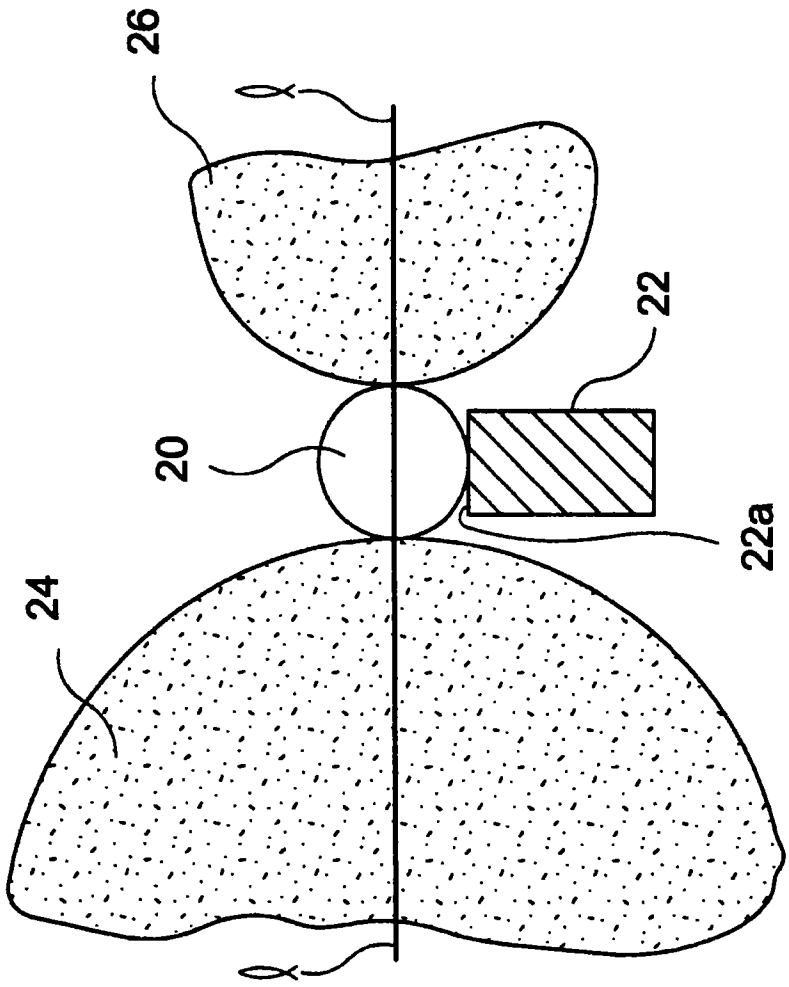


FIG-5

GUIDEWIRE HAVING A COATED TIP

CROSS-REFERENCE TO RELATED APPLICATION

The present application is a divisional of co-owned U.S. Ser. No. 08/496,956, filed Jun. 30, 1995, pending, which is hereby incorporated by reference.

FIELD OF THE INVENTION

The present invention relates generally to a guidewire for guiding a catheter through a body lumen such as the vascular system. More particularly, the present invention relates to a catheter guidewire having a coated distal tip portion which facilitates movement of the guidewire through the lumen.

BACKGROUND OF THE INVENTION

It has long been known to use guidewires for guiding catheters through body lumens for various medical procedures. One application in which such guidewires are typically used is in the percutaneous delivery of a catheter into the vascular system. The guidewire is a long flexible metal wire which may be inserted into the body percutaneously and advanced through the vascular system to the desired location. The guidewire may then be used as a vehicle for transporting an accompanying catheter to the given location.

In order to negotiate a tortuous path through the vascular system and to avoid obstacles during insertion, guidewires may include a curved flexible distal tip which can adapt itself to the shape of the blood vessel so that it can be advanced through such curved vessel without injuring the walls of the vessel. However, it is also important for the guidewire to exhibit sufficient rigidity such that the guidewire can be pushed forward without buckling or kinking. Further, proper advancement of the guidewire requires that the guidewire exhibit steerability. That is, the guidewire must be capable of being rotated so as to traverse curved portions of the vessel. Accordingly, the guidewire must also exhibit substantial torsional rigidity so that rotation of a proximate shaft portion causes corresponding rotation of the distal tip.

Guidewires of the type described herein are especially useful in procedures such as percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). In these procedures, the guidewires may be used to guide a balloon dilatation catheter to a stenosis in the blood vessel where upon the balloon of the guidewire is directed to the stenosis and the balloon is inflated thereby breaking apart the stenosed area of the vessel. Many guidewires, especially those used for PTCA procedures, are of relatively small diameter having an outer diameter not exceeding 0.018". The maximum diameter of a guidewire is limited by the internal diameter of the guidewire lumen in the balloon dilation catheter and by the vessel through which it must traverse.

The art has seen many attempts to provide guidewires which combine a relatively rigid shaft portion exhibiting substantial torsional rigidity and steerability and a flexible distal tip portion which facilitates traverse of the guidewire through the vascular system.

U.S. Pat. No. 4,925,445 describes a guidewire including a shaft portion and a distal tip portion which are formed from a superelastic TiNi alloy. The superelastic TiNi material enhances bendability and kink resistance of the guidewire. The entire guidewire may include a plastic coating thereover which enhances the ability of the guidewire to safely traverse the vascular system. The plastic coating may also contain an x-ray contrast medium such as metal particles therein which enhances the radiopacity of the guidewire.

However it has been found that with small sized guidewires such as those used for PCTA procedures, it is difficult to place a uniformly thin plastic coating thereover or if the guidewire is coated, the shaft may not exhibit the desired stiffness. Further, it is desirable in many instances to limit the plastic coating to the tip portion alone. This type of construction, with a coated tip portion and an uncoated shaft portion, helps transmit torque directly from the shaft portion to the tip portion resulting in enhanced steerability and maximum shaft stiffness. However, it is extremely difficult to coat only the flexible, thin distal tip portion of the guidewire. Attempts to coat the entire guidewire and selectively remove the coating from the shaft portion result in the coated tip portion having a larger diameter than the shaft portion.

It is also known to employ low friction hydrophilic coatings over guidewires. The hydrophilic coating increases the lubricity of the guidewire and allows the guidewire to more easily be maneuvered through tortuous areas of the vascular system. Examples of hydrophilic coatings in guidewire applications are found in U.S. Pat. Nos. 5,129,890 and 5,213,111.

However, none of the prior art techniques has been found to be suitable in providing a plastic coating at the distal tip of the guidewire where the overall diameter of the guidewire is not increased, so that the guidewire may still be used in locations requiring small diameters and allowing the guidewire to be passed through catheters having an internal luminal diameter which closely approximates the diameter of the shaft.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a method of forming a guidewire having a coated distal tip portion.

It is a further object of the present invention to provide a catheter guidewire having a proximal shaft portion and a distal tip portion and wherein the distal tip portion includes a coating thereover, the outer diameter of which is no greater than the diameter of the shaft portion.

It is a still further object of the present invention to provide a method of forming a catheter guidewire where a generally tubular coating is applied over the distal tip portion of the guidewire and the generally tubular coating is reduced so as to have a diameter no greater than the diameter of the shaft portion.

In the efficient attainment of these and other objects, the present invention provides a method of forming a guidewire assembly for a catheter. The method includes providing a guidewire having a proximal shaft portion and a distal tip portion where the diameter of the guidewire decreases from the shaft portion to the tip portion. A generally tubular coating is applied to at least the tip portion of the guidewire. The tubular coating has an outer diameter which is greater than the diameter of the shaft portion. The tubular coating is then reduced at the tip portion to a uniform outer diameter which is no greater than the diameter of the shaft portion.

As particularly described by way of the preferred embodiment herein, the reducing may be accomplished by centerless grinding where the tubular coating is ground to a uniform diameter no greater than the diameter of the shaft portion. Further, in the preferred embodiment, a hydrophilic coating may be disposed over the entire guidewire. The hydrophilic coating may be applied in two layers, a first

layer of an acrylic latex applied directly over the guidewire and a second layer of a homo or copolymer of acrylic amide which is disposed over the first layer.

The present invention further provides a guidewire assembly including an elongate guidewire core. The core includes a proximal shaft portion of given diameter, a distal tip portion of diameter less than that of the shaft portion and a transition shoulder of decreasing diameter therebetween. A plastic coating extends over the distal tip portion and the transition shoulder. The plastic coating has an outer diameter that is no greater than substantially the outer diameter of the shaft portion.

As particularly disclosed, the plastic coating has a uniform diameter over the tip portion which is equal to the diameter of the uncoated shaft portion so that a smooth transition is provided over the transition shoulder.

As is further described herein, the tubular coating may include an x-ray contrast medium such as metal particles which increase the radiopacity of the coated guidewire. In addition, the metal particles also increase the decomposition temperature of the plastic coating without unduly increasing the viscosity of the melt for the formation of the plastic coating.

The guidewire of the present invention may be formed of stainless steel or a superelastic metallic material such as a TiNi alloy. Further, the shaft portion of the guidewire may be formed of stainless steel while the tip portion of the guidewire be formed from the superelastic metallic material.

BRIEF DESCRIPTION OF THE DRAWING

FIG. **1** shows in cross section an end extent of a wire used to form the guidewire assembly of the present invention.

FIG. **2** is a sectional showing similar to FIG. **1** of the guidewire assembly of the present invention including a plastic coating thereover.

FIG. **3** is a sectional showing of a guidewire assembly of FIG. **2** with the plastic coating reduced in diameter.

FIG. **4** is a sectional showing of the guidewire assembly of FIG. **3** including a hydrophilic coating placed thereover.

FIG. **5** is a schematic representation of a centerless grinding process used in accordance with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention as shown in the drawings includes a guidewire assembly **10** which comprises a guidewire core **10***a* and one or more coatings which will be described in detail hereinbelow.

Core **10***a* is an elongate generally cylindrical wire member having a proximal shaft portion **11** and a distal tip portion **12**. The shaft portion **11** is generally uniformly cylindrical having a given outer diameter D. The tip portion **12** includes three longitudinally successive sections **13**, **14** and **15** which extend respectively from shaft portion **11**. Sections **13**, **14** and **15** are of successively decreasing diameter. The furthest distal extent of core **10***a* ends in a distal tip end **16**. Between tip portion **12** and shaft portion **11** a transition shoulder **12***a* is defined. Transition shoulder **12***a* is generally a tapered member tapering from a wider diameter adjacent shaft portion **11** to a narrower diameter adjacent tip portion **12**.

Shaft portion **11** of core **10***a*, in the preferred embodiment, is formed of stainless steel. While other metals may also be used, stainless steel is preferred as it imparts sufficient rigidity to guidewire assembly **10** resulting in a high degree of torsional stability as well as pushability to enable the guidewire to be inserted through the vascular system.

The pushability of a guidewire is defined as the force necessary to push the guidewire a given distance through the vascular system. The pushability of a guidewire depends upon the resistance against deflection of the shaft when the distal end of the guidewire is abutted against an obstruction such as a stenosis or a curved portion of the vessel. The pushability of the guidewire allows the guidewire to be advanced past the obstruction or the curve without buckling or kinking.

The tip portion **12** of guidewire core **10***a* may also be formed from metal. In the preferred embodiment, tip portion **12** is formed from a superelastic (pseudoelastic) metallic material. As is well known, such superelastic material may include a titanium nickel (TiNi) alloy. The use of such a superelastic material allows for high flexural deformation to be obtained under a comparatively low load such that the tip portion **12** is capable of being highly flexed and returned to its original shape once the load has been relieved. The use of a superelastic tip portion **12** allows the guidewire to traverse a tortuous path through the vascular system without creating a permanent bend or kink in the tip portion. While TiNi is described as the preferred superelastic alloy, other well known superelastic alloys may also be employed. Further, it is contemplated that the entire guidewire core **10***a* may be formed of a uniform material of stainless steel or superelastic metal.

In order to render the guidewire assembly **10** more capable of easy traverse through the vascular system, the present invention provides for the placement of a coating on at least the tip portion **12** of guidewire assembly **10**. As particularly shown in FIG. **2**, a tubular plastic coating **17** is disposed over tip portion **12** and also may be placed over shaft portion **11**. The tubular plastic coating **17** may be applied in a variety of known application techniques. One technique which may be employed to apply tubular coating **17** is to extrude the coating over core **10***a* which is passed through the center of an annular extrusion die to extrude the plastic thereover. Another technique may be to injection mold the tubular coating over core **10***a* or in the alternative, the core **10***a* may be repeatedly dipped in a suspension dispersion or solution of the material forming the coating. If the latter technique is used, each layer of coating is dried before an additional coating layer is applied. Additionally, the term "coating" as used hereinthroughout, shall also encompass the placement of a covering, such as a separate sheath over core **10***a*.

In a preferred embodiment, the tubular coating is a plastic coating which is preferably made from a polyether block amide but also may be formed from other materials such as an elastomer, polyethylene, polypropylene, polyvinylchloride, polyester, polyamide, polyurethane, fluorine plastics and silicone rubber or an elastomer or a composite material of the above-mentioned materials.

Further, the plastic coating **17** may include an x-ray contrast medium which enhances the radiopacity of the guidewire. Such x-ray contrast medium may include metal particles such as barium, tungsten, bismuth or lead particles which are present in the plastic coating **17** which is placed on core **10***a*.

The concentration of metal particles is preferably between 7 and 14% volume/volume and more preferably in a concentration of between 9 and 13.5% volume/volume. It is also

preferable that the particle size of the metal particles be between 1 and 8 μm, especially where tungsten particles are used as the x-ray contrast medium.

The use of a relatively high concentration of metal particles in coating **17** in addition to improving the radiopacity of the guidewire assembly **10** also increases the decomposition temperature of the plastic material formed in the coating without unduly increasing the viscosity of melt or the formation of the plastic coating. Thus, the decomposition temperature of a preferred plastic coating containing tungsten particles of concentration of about 5.6% volume/volume is about 190° C. The decomposition temperature of the same plastic containing tungsten particles in concentrations of 7.3%, 10.9%, and 13.5% volume/volume is 196.4° C., 214.2° C. and 204.7° C. respectively. Thus, it can be seen that the decomposition temperature of the plastic is greatly increased by the addition of metal particles. It has been found that the viscosity of the plastic melt containing such increased amounts of tungsten is such that the momentum of such melt is between 1 and 10 nm determined by means of a Brabender mixer. Such viscosity has been found to be suitably acceptable for use in conventional extruders.

While the above technique is disclosed herein, x-ray contrast may also be achieved by placing one or more conventional gold rings or similar members directly on the tip core prior to placing the plastic coating thereon.

It is also preferred that the plastic coating **17** may contain additives such as an anticoagulating agent and an antithrombis material which facilitates use of the guidewire assembly in the vascular system.

In the efficient manufacture of the guidewire assembly **10** of the present invention, the plastic coating is placed on tip portion **12** and over shaft portion **11**. Ultimately it is desirable to construct a guidewire assembly **10** with only the tip portion **12** including a plastic coating **17**, as an uncoated shaft portion **11** allows torque to be transmitted to the tip portion directly with close to a 1:1 ratio and also obtains maximum shaft stiffness. However, in small sized guidewire (less than 0.018") having a thin flexible distal tip portion **12**, it is extremely difficult to coat only the tip portion. The present invention therefore contemplates removal of that portion of the coating from the shaft portion **11** prior to further processing. The plastic coating may be removed from the shaft portion **11** by any well known technique. This results in an uncoated shaft portion **11**. In addition to improving the torsional stability and shaft stiffness, removal of the plastic coating **17** from shaft portion **11** also results in the overall outer diameter of the core **10***a* being kept to a minimum.

Referring now to FIG. **3**, the tubular coating **17** at tip portion **12** may now be reduced to a uniform outer diameter which does not exceed the outer diameter of shaft portion **11** of core **10***a*. In the preferred embodiment of the present invention, the tubular portion **17** is reduced to a desired uniform diameter which is substantially equal to the diameter D of the uncoated shaft portion **11**. This results in a smooth transition between tip portion **12** and shaft portion **11** over transition shoulder **12***a*.

It has been found that a preferred process for the removal of the plastic coating **17** from tip portion **11** is by centerless grinding. Centerless grinding is a well known grinding technique which is typically used to impart cylindrical surfaces to elongate articles such as steel bars and the like that are either too long or too flexible for the ends of the bars to be mounted between center supports.

As shown schematically in FIG. **5**, in centerless grinding, the workpiece **20** rests on a work support blade **22** and is forced against the "grinding wheel" **24** by the "regulating" or "feed wheel" **26** which controls the speed of work rotation and the rate of work travel through the machine.

The centerline l of the wheels is the straight line joining the center of the grinding wheel **24** and the center of the regulating wheel **26** in the reference plane.

The reference plane is the plane perpendicular to the axis of the grinding wheel and passing through the point where the axis of the regulating wheel goes through the horizontal plane which runs through the axis of the grinding wheel.

In a plane perpendicular to the axis of the grinding wheel **24**, the circle cutting the workpiece **20** is tangent to the two circles cutting the regulating wheel **26** and the grinding wheel **24** and to the perpendicular section through the bearing surface **22***a* of the blade **22**.

While traditionally limited to steel bar stock and the like, it has been found that centerless grinding may be employed in accordance with the present invention for reducing the diameter of the plastic coating **17** applied to the tip portion **12** of a guidewire core **10***a*. It has further been found that with small sized guidewires such as that less than 0.018", the outer diameter of the plastic coating **17** can be uniformly reduced so as to obtain a tip portion **12** having both a radially and axially uniform coating thickness therealong.

Centerless grinding allows for the reduction of the tip portion **12**, which would not otherwise be achievable due to the thin and flexible nature of the tip portion. The resulting guidewire has a uniform thickness and achieves a smooth transition between the tip portion **12** and shaft portion **11**. In addition, the grinding process results in a uniform coating **17** being applied over tip portion **12** where the tip portion includes successive portions **13**, **14** and **15** of longitudinally successive decreasing diameters. Thus, notwithstanding the tapering tip portion **12**, the outer diameter of the plastic coating **17** remains constant therealong.

Centerless grinding has been found to be particularly suitable for the grinding of plastic coating **17** which contains an x-ray medium in the form of metallic particles.

As mentioned above, the present invention contemplates grinding the tubular coating **17** to an overall outer diameter which is substantially equal to diameter D (FIG. **1**) of shaft portion **11** of core **10***a*. In this manner, while the distal tip portion **12** includes a coating **17** thereover, the coating does not increase the overall diameter of the core **10***a* thus allowing the guidewire assembly **10** to be used in areas where small sized guidewires are required.

Optionally, to increase the lubricity of the guidewire assembly **10** so as to reduce friction between the guidewire assembly and the surrounding vascular structure through which it is inserted, a hydrophilic coating **19** such as shown in FIG. **4** may be employed. Hydrophilic coating **19** is of the type shown and described in commonly assigned International Patent Publication WO91/19756 which is incorporated by reference herein.

Hydrophilic coating **19** may be applied by applying a first inner layer of acrylic latex **19***a* and then applying a second outer layer of a homo or copolymer **19***b* of acrylic amide. However, other hydrophilic coating materials and techniques are also contemplated.

The invention may be further described with reference to the following example.

EXAMPLE

A metal wire consisting of a superelastic material of the type which is commercially available under the tradename

Tynel BC, has a total length of about 63" and a diameter of about 0.014". The metal wire itself is subjected to centerless grinding so as to provide a distal tip having a length of about 16" comprising three successively tapering sections having diameters of about 0.013", 0.011" and 0.008". A tubular plastic coating having an outer diameter of about 0.020" on the shaft and an outer diameter of about 0.018" at the tip, is applied over the metal wire by extrusion. The plastic coating is prepared from a polyether block amide commercially available under the tradename PEBAX containing tungsten particles in a concentration of 10.9% volume/volume and having a decomposition temperature of 214.2° C. The metal wire is advanced through an orifice of an extruder at a speed of about 5 meters per minute. Subsequently the plastic coating is removed from the shaft of the metal wire and the plastic coated tip is mounted in a centerless grinding machine. The plastic coating is then ground and during the grinding process a coolant is supplied to the surface of the plastic coating to make it smooth. After grinding the outer diameter of the plastic coating is ground to 0.014" approximately the same diameter of the shaft portion of the metal wire. A thin uniform hydrophilic coating is then applied over the full length of the guidewire.

Various changes to the foregoing described and shown structures would now be evident to those skilled in the art. Accordingly, the particularly disclosed scope of the invention is set forth in the following claims.

What is claimed:

1. A method of forming a guidewire assembly for a catheter comprising the steps of:

providing an elongate guidewire, said guidewire having a proximal shaft portion and a distal tip portion and a diameter which decreases from the shaft portion to the tip portion;

applying a generally tubular plastic coating over said proximal shaft portion and said distal tip portion of the guidewire;

removing said tubular coating from said proximal shaft portion; and

reducing said applied tubular coating on said tip portion to a diameter no greater than substantially equal to said shaft portion diameter.

2. A method of claim **1** wherein said reducing step includes:

reducing said tubular coating over said tip portion to an outer diameter substantially equal to the outer diameter of said shaft portion to create a smooth transition therebetween.

3. A method of claim **1** wherein said reducing step includes:

centerlessly grinding said applied tubular coating.

4. A method of claim **1** further including the step of:

applying a hydrophilic coating over said reduced tubular coating.

5. A method of claim **1** further including the step of applying a hydrophilic coating over said tip portion and said shaft portion.

6. A method of claim **1** wherein said applying step includes:

injection molding said plastic coating over at least said tip portion.

7. A method of claim **1** wherein said applying step includes:

extruding said plastic coating over at least said tip portion.

8. A method of claim **1** wherein said applying step includes:

applying said plastic coating over at least said tip portion by dipping.

9. A method of claim **1** wherein said plastic coating is formed from polyether block amide.

10. A method of claim **1** wherein said tubular coating includes an x-ray contrast medium.

11. A method of claim **10** wherein said x-ray contrast medium includes metal particles.

12. A method of claim **11** wherein said metal particles are tungsten particles having a particle size of between about 1 to 8 μm.

13. A method of claim **1** wherein said shaft portion is formed from steel.

14. A method of claim **13** wherein said tip portion is formed from steel.

15. A method of claim **1** wherein said tip portion is formed from superelastic material.

16. A method of claim **15** wherein said shaft portion is formed from superelastic material.

17. A method of claim **15** wherein said superelastic material is a TiNi alloy.

18. A method of claim **5** wherein said hydrophilic coating applying step further includes:

applying a first layer of acrylic latex over said guidewire; and

applying a second layer of a homo or copolymer of acrylic amide over said first layer.

19. A method of coating a catheter guidewire, said guidewire having a proximal shaft having a given diameter and a distal tip having a diameter less than said given diameter, said method comprising the steps of:

applying a coating over said guidewire;

removing said coating from said proximal shaft; and

reducing said coating over said tip to an outer diameter no greater than said given shaft diameter.

20. A method of claim **19** wherein said reducing step includes:

grinding said coating.

21. A method of claim **20** wherein said grinding step further includes:

grinding said coating by centerless grinding.

22. A method of claim **19** further including the step of:

applying a hydrophilic coating over said coated guidewire.

23. A method of claim **19** wherein said coating is a plastic coating.

24. A method of claim **23** wherein said plastic coating includes an x-ray contrast medium.

25. A method of claim **22** wherein said hydrophilic coating step includes:

applying a first layer of acrylic latex over said guidewire; and

applying a second layer of a homo or copolymer of acrylic amide over said first layer.

* * * * *

EXHIBIT 4

US006296616B1

(12) **United States Patent**
McMahon

(10) **Patent No.: US 6,296,616 B1**
(45) **Date of Patent: Oct. 2, 2001**

(54) **GUIDEWIRE WITH SHAPED INTERMEDIATE PORTION**

(75) Inventor: **James C. McMahon**, Temecula, CA (US)

(73) Assignee: **Advanced Cardiovascular Systems, Inc.**, Santa Clara, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/518,499**

(22) Filed: **Mar. 3, 2000**

Related U.S. Application Data

(63) Continuation of application No. 08/972,654, filed on Nov. 18, 1997.

(51) **Int. Cl.**[7] **A61B 5/00**
(52) **U.S. Cl.** **600/585**; 604/523
(58) **Field of Search** 600/585, 433, 600/434; 604/523

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,731,671	5/1973	Mageoh	128/2.05 R
3,928,519	12/1975	Kashiyama et al.	264/40
4,080,706	3/1978	Heilman et al.	29/173
4,534,363	8/1985	Gold	128/772
4,538,622	9/1985	Samson et al.	128/772
4,724,846	2/1988	Evans III	128/772
4,748,986	6/1988	Morrison et al.	128/772
4,807,596	2/1989	Hochberger et al.	128/4
4,840,623	6/1989	Quackenbush	604/280
5,061,273	10/1991	Yock	606/194
5,095,915	3/1992	Engelson	128/772
5,135,503	8/1992	Abrams	604/164
5,147,317	9/1992	Shank et al.	604/164
5,341,818	8/1994	Abrams et al.	128/772
5,345,945	9/1994	Hodgson et al.	128/772
5,358,493	10/1994	Schweich, Jr. et al.	604/264
5,404,887	4/1995	Prather	128/772
5,497,785	3/1996	Viera	600/585
5,507,729	4/1996	Lindenberg et al.	604/170
5,516,336	5/1996	McInnes et al.	606/194
5,551,443	9/1996	Sepetka et al.	600/585
5,606,979	3/1997	Hodgson	128/772
5,827,201	10/1998	Samson et al.	600/585

FOREIGN PATENT DOCUMENTS

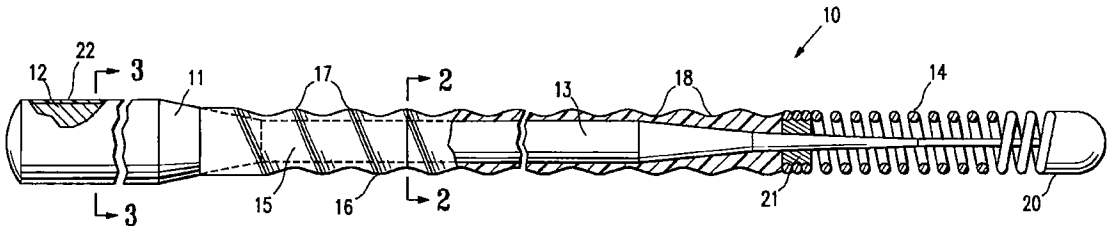
0 377 453 A1	11/1990	(EP) .
WO 89/10088	2/1989	(WO) .
WO 92/14508	3/1992	(WO) .

Primary Examiner—Robert L. Nasser
Assistant Examiner—Pamela L Wingood
(74) *Attorney, Agent, or Firm*—Heller, Ehrman, White & McAuliffe

(57) **ABSTRACT**

A guidewire for advancing a medical device such as a catheter through a patient's body lumen which has an elongated core with proximal and distal core sections, a flexible tubular member such as a coil on the distal end and an intermediate portion, preferably formed at least in part by a polymeric sheath proximal to the coil having contact regions and recessed non-contact regions.

16 Claims, 2 Drawing Sheets



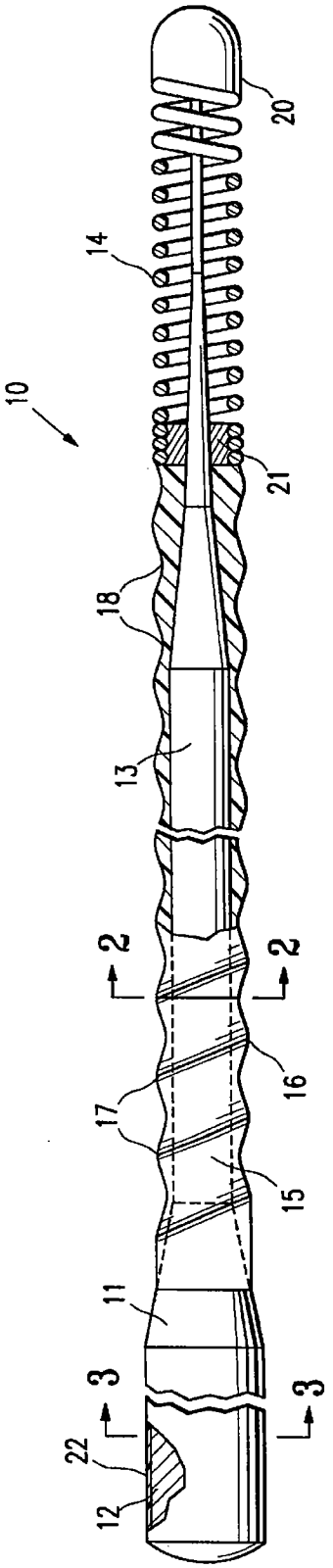


FIG. 1

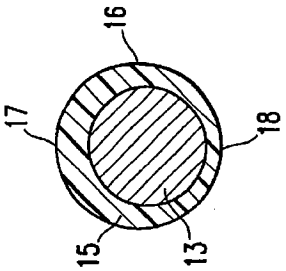


FIG. 2

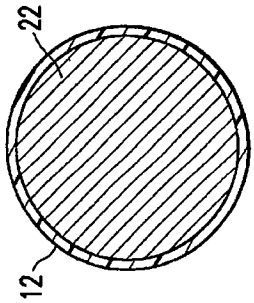


FIG. 3

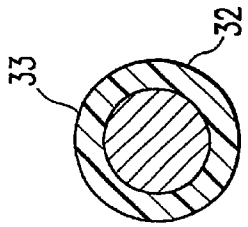


FIG. 5

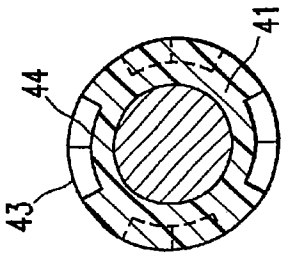


FIG. 7

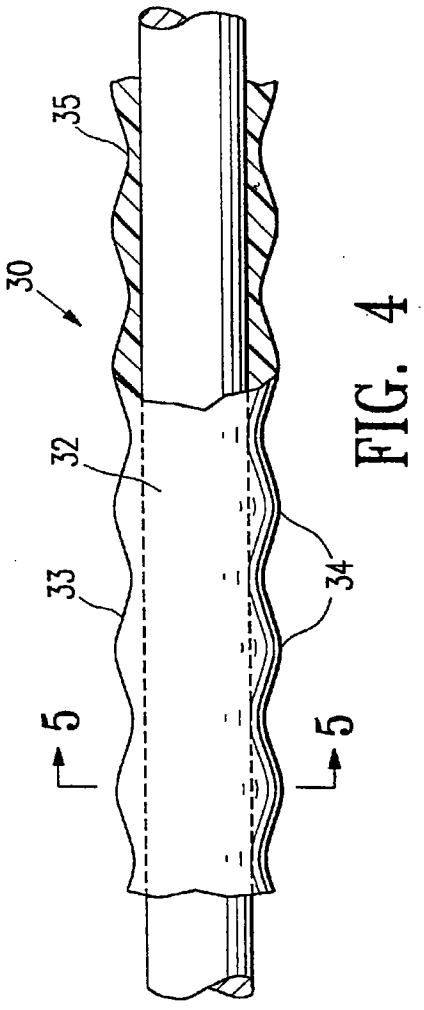


FIG. 4

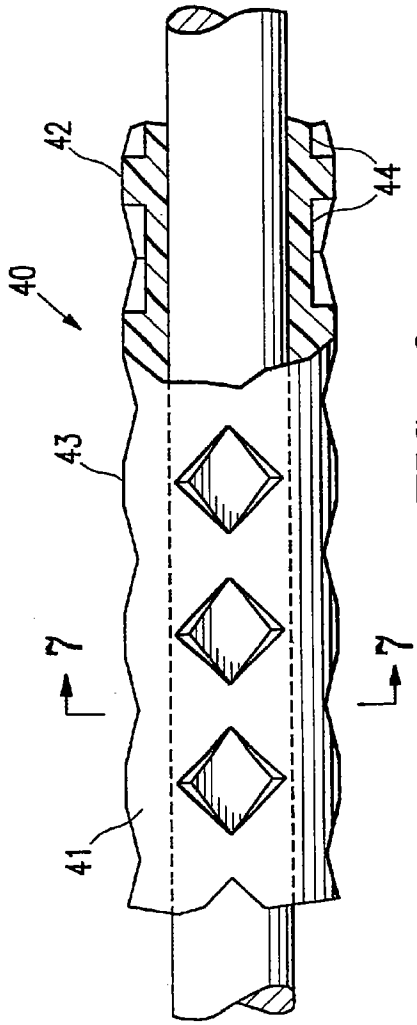


FIG. 6

GUIDEWIRE WITH SHAPED INTERMEDIATE PORTION

This is a continuation application of copending application Ser. No. 08/972,654 filed Nov.18, 1997, incorporated by reference.

BACKGROUND OF THE INVENTION

This invention relates to the field of guidewires for advancing intravascular devices such as stent delivery catheters, balloon dilatation catheters and atherectomy catheters within a body lumen

Conventional guidewires for angioplasty, stent delivery, atherectomy and other vascular procedures usually comprise an elongated core member with one or more tapered sections near the distal end thereof and a flexible body such as a helical coil or a tubular body of polymeric material disposed about the distal portion of the core member. A shapable member, which may be the distal extremity of the core member or a separate shaping ribbon which is secured to the distal extremity of the core member extends through the flexible body and is secured to the distal end of the flexible body by soldering, brazing or welding which forms a rounded distal tip. Torquing means are provided on the proximal end of the core member to rotate, and thereby steer, the guidewire while it is being advanced through a patient's vascular system.

Further details of guidewires, and devices associated therewith for various interventional procedures can be found in U.S. Pat. No. 4,748,986 (Morrison et al.); U.S. Pat. No. 4,538,622 (Samson et al.): U.S. Pat. No. 5,135,503 (Abrams); U.S. Pat. No. 5,341,818 (Abrams et al.); and U.S. Pat. No. 5,345,945 (Hodgson, et al.) which are hereby incorporated herein in their entirety by reference thereto.

In a typical coronary procedure using a guidewire, a guiding catheter having a preformed distal tip is percutaneously introduced into a patient's peripheral artery, e.g. femoral or brachial artery, by means of a conventional Seldinger technique and advanced and steered therein until the distal tip of the guiding catheter is seated in the ostium of a desired coronary artery.

There are two basic techniques for advancing a guidewire into the desired location within the patient's coronary anatomy through the in place guiding catheter. The first is a preload technique which is used primarily for over-the-wire (OTW) devices and the second is the bare wire technique which is used primarily for rail type systems.

With the preload technique, a guidewire is positioned within an inner lumen of an OTW device such as a dilatation catheter or stent delivery catheter with the distal tip of the guidewire just proximal to the distal tip of the catheter and then both are advanced through the guiding catheter to the distal end thereof. The guidewire is first advanced out of the distal end of the guiding catheter into the patient's coronary vasculature until the distal end of the guidewire crosses the arterial location where the interventional procedure is to be performed, e.g. a lesion to be dilated or a dilated region where a stent is to be deployed. The catheter, which is slidably mounted onto the guidewire, is advanced out of the guiding catheter into the patient's coronary anatomy over the previously introduced guidewire until the operative portion of the intravascular device, e.g. the balloon of a dilatation or a stent delivery catheter, is properly positioned across the arterial location. Once the catheter is in position with the operative means located within the desired arterial location, the interventional procedure is performed. The catheter can then be removed from the patient over the guidewire. Usually, the guidewire is left in place for a period of time after the procedure is completed to ensure reaccess to the arterial location is it is necessary. For example, in the event of arterial blockage due to dissected lining collapse, a rapid exchange type perfusion balloon catheter such as described and claimed in U.S. Pat. No. 5,516,336 (McInnes et al), can be advanced over the in-place guidewire so that the balloon can be inflated to open up the arterial passageway and allow blood to perfuse through the distal section of the catheter to a distal location until the dissection is reattached to the arterial wall by natural healing.

With the bare wire technique, the guidewire is first advanced by itself through the guiding catheter until the distal tip of the guidewire extends beyond the arterial location where the procedure is to be performed. Then a rail type catheter, such as described in U.S. Pat. No. 5,061,395 (Yock) and the previously discussed McInnes et al. which are incorporated herein by reference, is mounted onto the proximal portion of the guidewire which extends out of the proximal end of the guiding catheter which is outside of the patient. The catheter is advanced over the catheter, while the position of the guidewire is fixed, until the operative means on the rail type catheter is disposed within the arterial location where the procedure is to be performed. After the procedure the intravascular device may be withdrawn from the patient over the guidewire or the guidewire advanced further within the coronary anatomy for an additional procedure.

SUMMARY OF THE INVENTION

The present invention is directed to an improved guidewire having a flexible distal section which facilitates advancement through a patient's body lumen.

The guidewire of the present invention has an elongated core member with proximal and distal core sections with a flexible tubular member such as a helical coil is disposed about and secured to the distal part of the distal core section. The distal core section has one or more distally tapering segments. Proximal to the flexible tubular member, the guidewire has an exterior surface which is shaped to provide a plurality of contact regions and non-contact regions between adjacent contact regions.

In one presently preferred embodiment, the intermediate portion is defined by a sheath disposed about the core member and preferably formed of a polymeric material. The contact region or regions of the intermediate portion of the guidewire is generally about 20 to about 60% of the surface of the sheath. The outer diameter of the contact regions of the intermediate portion is preferably the same or approximately the same as the outer diameter of the flexible tubular member or coil on the distal part of the distal shaft section. However, if the flexible tubular member is of different outer diameter than the proximal core section, the intermediate portion may taper from the outer diameter of the proximal core section to the outer diameter of the coil. The distances between the peaks of the contact regions should be about 0.05 to about 5.0 mm, preferably about 0.1 to about 0.5 mm. The depth of the recessed non-contact regions may be about 0.01 to about 0.1 mm, preferably about 0.025 to about 0.075 mm as measured from the peaks of the contact regions. While the presently preferred intermediate portion of the guidewire having the contact and non-contact regions extends distally from the flexible tubular member and terminates distal to the proximal core section, the section having the contact and non-contact regions can extend proximally over most or all of the proximal core section.

By reducing the area of surface contact between the guidewire and a body lumen or a catheter lumen in which the guidewire is being moved relative thereto, the resistance to movement is greatly reduced. In one embodiment of the invention, solid or liquid lubricant can be maintained within recessed non-contact regions to further reduce frictional drag on the guidewire as it moves through a lumen or the frictional drag on a catheter as the catheter is moved over the intermediate portion of the guidewire. Pharmaceutical materials and diagnostic and therapeutic agents may also be incorporated into the recessed non-contact regions.

In one presently preferred embodiment of the invention, the intermediate guidewire portion having the contact and non-contact regions is defined by an intermediate sheath disposed about at least part of the distal guidewire section proximal to the flexible tubular member or coil on the distal part of the distal section.

These and other advantages of the invention will become more apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an elevational view partially in section of a guidewire embodying features of the invention wherein a sheath forming the intermediate portion has a helically shaped ridge.

FIG. **2** is a transverse cross-sectional view of the guidewire shown in FIG. **1** taken along the lines **2—2**.

FIG. **3** is a transverse cross-sectional view of the guidewire shown in FIG. **1** taken along the lines **3—3**.

FIG. **4** is an elevational view partially in section of an alternative embodiment of the invention wherein a sheath on the intermediate portion has an undulating exterior surface.

FIG. **5** is a transverse cross-sectional view of the embodiment shown in FIG. **4** taken along the lines **5—5**.

FIG. **6** is an elevational view partially in section of an alternative embodiment of the invention wherein the intermediate section has a closed figure design formed into the exterior surface thereof.

FIG. **7** is a transverse cross-sectional view of the embodiment shown in FIG. **6** taken along the lines **7—7**.

DETAILED DESCRIPTION OF THE INVENTION

FIGS. **1–3** depict a guidewire **10** embodying features of the invention which has an elongated core member **11** with a proximal core section **12**, a distal core section **13** and a helical coil **14** on the distal extremity of the distal core section. An intermediate portion of the guidewire **10** proximal to the helical coil **14** is provided with a sheath **15**, which is disposed about and secured to the distal core section **13**, has an exterior surface **16** with contact regions **17** in the form of a helical ridge and a plurality of recessed (with respect to the contact regions) non-contact regions **18** disposed between adjacent contact regions. The peak-to-peak distance between the adjacent contact regions **17** is about 0.05 to about 5 mm, preferably about 0.1 to about 0.5 mm.

The distal end of coil **14** is secured to the distal tip of the distal core section **13** by suitable means, such as solder, a weldment, an adhesive, a body of polymeric material and the like which forms the rounded tip **20**. The proximal end of the coil **14** is secured to the distal core section by solder **21**. The proximal core section **12** has a polymeric jacket **22** which is preferably formed of lubricious polymeric materials such as fluoropolymers or hydrophilic materials. Other lubricious materials may be utilized.

An alternative embodiment of the invention is depicted in FIGS. **4** and **5** wherein the guidewire **30** has an intermediate portion proximal to the helical coil **31** covered with a sheath **32** which has an undulating exterior surface **33** with contact regions **34** in the form of a plurality of circular ridges and a plurality of recessed non-contact regions **35** between adjacent contact regions. The peak-to-peak distances between the contact surfaces **34** of this embodiment are the same or approximately the same as that for the contact regions **17** of the previously described embodiment.

FIGS. **6** and **7** illustrate yet another alternative embodiment of the invention in which the guidewire **40** has an intermediate portion with a sheath **41** with a closed figure texture formed in the exterior surface **42** with contact regions **43** and recessed non-contact regions **44** for essentially the same purpose as the contact and non-contact regions of the previously discussed embodiments. The recessed non-contact regions may contain liquid or solid lubricant such as a fluoropolymer, a silicone coating such as MICROGLIDE™, or HYDROCOAT™. These recesses may also be employed as reservoirs for pharmaceutical materials, therapeutic agents or diagnostic agents.

The sheaths forming the intermediate portions of the guidewires of the present invention may be formed by first heat shrinking a thermoplastic polymeric material onto the distal core section proximal to the coil and then placing a clam-shell mold of the desired configuration about the heat shrunk material at elevated temperatures to shape the exterior of the intermediate sheath in the desired configuration. Other means may also be employed. For example, the exterior surface of a tubular polymeric member may first be formed into the desired shape and then the tubular member heat shrunk onto the distal core section. Other means including casting polymeric material about the distal core section into the desired shape. Machining polymeric material from the exterior of a tubular polymeric member on the distal core segment may also be employed to develop the contact and non-contact regions of the intermediate sheath. Suitable polymeric materials for the intermediate sheath include polyethylene, polyetheretherketone, polyvinyl chloride and polyurethane. A wide variety of other polymeric materials are contemplated. The sheathed intermediate portion of the guidewire is about 4 to about 38 cm in length, preferably about 6 to about 20 cm in length.

The guidewires of the invention may have typical guidewire dimensions. Guidewire length may generally be about 90 to about 300 cm, and for use within a patient's coronary anatomy commercially available guidewires are typically about 175 cm in length. Recently, however, longer guidewires, e.g. up to 190 cm in length, are being offered commercially by a variety of suppliers, including the present assignee. The proximal core section **12** may have a length of about 65 to about 280 cm, preferably about 150 to about 200 cm and a diameter generally about 0.008 to about 0.035 inch (0.20–0.89 mm), typically about 0.010 to about 0.020 inch (0.25–0.51 mm) for coronary artery uses. The distal core section is preferably much shorter than the proximal core section and generally is about 6 to about 40 cm, preferably about 8 to about 30 cm in length and tapers in the distal direction in one or more steps to smaller transverse dimensions.

The core member is preferably coated with a lubricous coating such as a fluoropolymer, e.g. TEFLON ® available from DuPont, which extends the length of the proximal core

section 12. The distal section 13 is also provided a lubricous coating, not shown for purposes of clarity, such as a MICROGLIDE ™ coating used by the present assignee, Advanced Cardiovascular Systems, Inc. on many of its commercially available guidewires.

The tapered portion of the distal core segment is preferably followed distally with a manually shapable flattened core segment or shaping ribbon of about 1 to 4 cm in length which preferably has essentially constant transverse dimensions, e.g. 0.0005–0.002 inch (0.013–0.051 mm) by 0.002–0.006 inch (0.051–0.152 mm), typically about 0.001 by 0.003 inch (0.025–0.076 mm). A helical coil having transverse outer dimensions about the same as or slightly less than the proximal core section is secured by its distal end to the flattened distal tip of the core member, e.g. by means of solder, and by its proximal end at an intermediate position on the tapered distal core segment so that the distal end of the tapered core segment resides within the interior of the coil. The helical coil 14 may be formed all or in part of stainless steel, a suitable radiopaque material such as platinum or alloys thereof or other material such as stainless steel coated with a radiopaque material such as gold. The wire from which the coil is made generally has a transverse diameter of about 0.0015 to about 0.003 inch (0.04–0.08 mm) for coronary applications and up to 0.07 inch (0.18 mm) for peripheral applications. The overall length of the coil 14 is about 2 to about 15 cm, preferably about 2 about 6 cm. Multiple turns of the coil 14 may be expanded to provide additional flexibility.

Unless otherwise described herein, conventional materials and manufacturing methods may be used to make the guiding members of the present invention. Additionally, various modifications may be made to the present invention without departing from the scope thereof. Although individual features of embodiments of the invention may be shown in some of the drawings and not in others, those skilled in the art will recognize that individual features of one embodiment of the invention can be combined with any or all the features of another embodiment.

What is claimed is:

1. A guidewire for intralumenal advancement of a medical device within a patient, comprising:

a) an elongated metallic core member which has a proximal core section and a distal core section;

b) a flexible body which is disposed about and secured to a portion of the distal core section; and

c) an intermediate non-metallic sheath which is disposed at a location proximal to the flexible body and which has an exterior with a plurality of contact regions and recessed non-contact regions disposed between contact regions.

2. The guidewire of claim 1 wherein the contact regions form a helical ridge on the exterior of the intermediate sheath which encircles the core member at least one time.

3. The guidewire of claim 1 wherein the contact regions form a plurality of circular ridges on the exterior of the intermediate sheath which are disposed about the core member.

4. The guidewire of claim 1 wherein the intermediate sheath has a closed figure texture formed in the exterior of the sheath with the contact regions surrounding non-contact regions.

5. The guidewire of claim 1 wherein recessed non-contact regions are configured to hold at least one component selected from the group consisting of a lubricant, a therapeutic agent and a diagnostic agent.

6. The guidewire of claim 1 wherein the non-metallic sheath is formed of a polymeric material.

7. The guidewire of claim 6 wherein the polymeric material is a heat shrunk thermoplastic.

8. The guidewire of claim 1 wherein the contact regions comprise about 20 to about 60% of the surface of the intermediate sheath.

9. The guidewire of claim 1 wherein the contact regions are spaced about 0.05 to about 5 mm.

10. The guidewire of claim 1 wherein the contact regions are spaced about 0.1 to about 0.5 mm.

11. The guidewire of claim 1 wherein the recessed non-contact regions have depths of about 0.01 to about 0.1 mm.

12. The guidewire of claim 1 wherein the recessed non-contact regions have depths of about 0.025 to about 0.075 mm.

13. The guidewire of claim 1 wherein the intermediate sheath has a proximal portion with an outer diameter approximately the same as the outer diameter of the proximal core section.

14. The guidewire of claim 1 wherein the intermediate sheath has a distal portion with an outer diameter approximately the same as the outer diameter of the flexible tubular member.

15. The guidewire of claim 1 wherein the intermediate sheath is about 4 to about 38 cm in length.

16. The guidewire of claim 1 wherein the intermediate sheath is about 6 to about 20 cm in length.

* * * * *

EXHIBIT 5

US006251085B1

(12) **United States Patent**
Tezuka

(10) **Patent No.: US 6,251,085 B1**
(45) **Date of Patent: Jun. 26, 2001**

(54) **MEDICAL GUIDEWIRE**

(75) Inventor: **Toshiaki Tezuka**, Kanagawa-ken (JP)

(73) Assignee: **Olympus Optical Co., Ltd.**, Tokyo (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/103,368**

(22) Filed: **Jun. 23, 1998**

(30) **Foreign Application Priority Data**

Jul. 4, 1997 (JP) 9-179972

(51) **Int. Cl.**[7] **A61B 5/00**

(52) **U.S. Cl.** **600/585**; 600/433; 604/95; 604/280

(58) **Field of Search** 600/585, 433, 600/434; 604/95, 96, 280, 281, 282

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,579,127		4/1986	Haacke .	
5,111,829		5/1992	Alvarez de Toledo .	
5,251,640	*	10/1993	Osborne	600/585
5,344,315	*	9/1994	Hanson	433/20
5,769,796	*	6/1999	Palermo et al.	600/585
5,827,201	*	10/1998	Samson et al.	600/585
5,910,364	*	6/1999	Miyata et al.	600/585
6,019,736	*	2/2000	Avellanet et al.	600/585

FOREIGN PATENT DOCUMENTS

33 27 779 A1	2/1985	(DE) .
0 826 389 A2	3/1998	(EP) .
61-7735	3/1986	(JP) .
62-231675	10/1987	(JP) .
2-180277	7/1990	(JP) .
2-40992	10/1990	(JP) .
WO 98/16274	4/1998	(WO) .

OTHER PUBLICATIONS

German Literature: Verlag Knaur, München: Grimm–Rapunzel, p. 103.

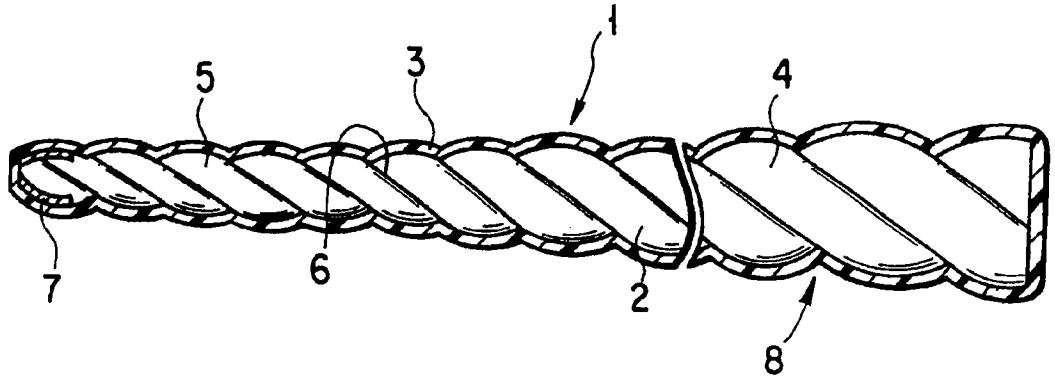
* cited by examiner

Primary Examiner—Cary O'Connor
Assistant Examiner—Pamela L. Wingood
(74) *Attorney, Agent, or Firm*—Frishauf, Holtz, Goodman, Langer & Chick, P.C.

(57) **ABSTRACT**

The present invention provides a guidewire having a reduced diameter, which ensures rigidity and excellent guidance ability in spite of its reduced diameter, and which achieves an excellent sliding ability and insertion/pulling-out ability with respect to a catheter or the like. The guidewire has an inner core formed of a single wire having an uneven surface on its outer circumferential surface, a high-polymer coating which densely covers the outer circumferential surface of the inner core, and an uneven surface formed on the outer circumferential surface of the high-polymer coating by an influence from the uneven surface on the outer circumferential surface of the inner core.

14 Claims, 1 Drawing Sheet



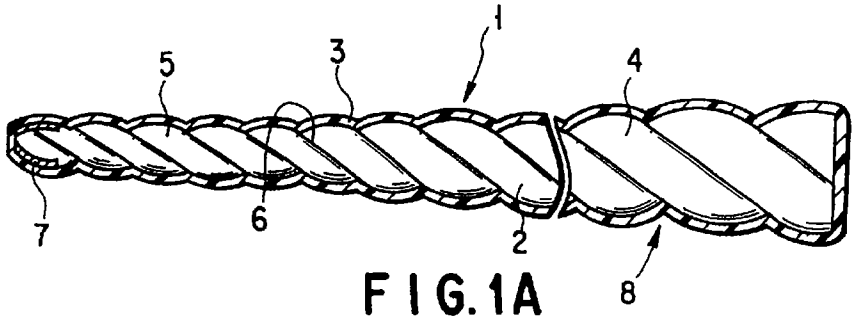


FIG. 1A

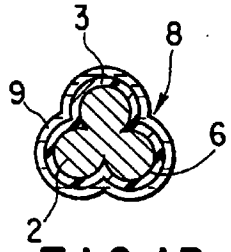


FIG. 1B

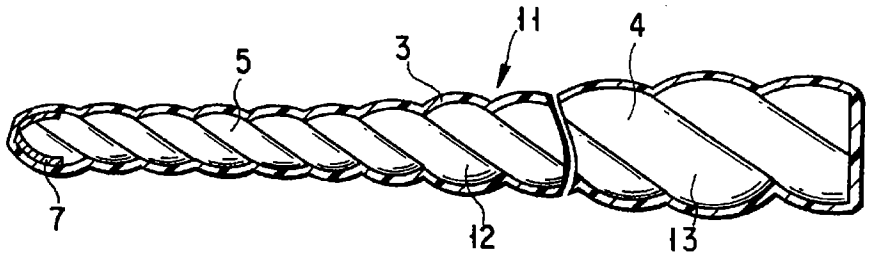


FIG. 2A

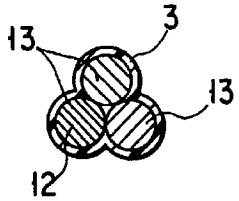


FIG. 2B

MEDICAL GUIDEWIRE

BACKGROUND OF THE INVENTION

The present invention relates to a guidewire for guiding a medical device having a hollow structure such as a catheter or the like, which is introduced into a human body directly or through an endoscope in a medical treatment or inspection.

In recent years, medical treatments have come to introduce positively a technique which makes less incision damages to a human body. Specifically, in place of an incision operation, such as abdominal section, thoracotomy or the like, which provides a heavy physical burden to a patient, an inspection and a treatment carried out by inserting various catheters into a human cavity have come to be used. In case of practicing such a technique, it is general that a guidewire is inserted through a catheter which is to be inserted into a human body and a device such as the catheter or the like is guided to an aimed body cavity portion along the guidewire. Many guidewires of this kind are used in an inspection or a treatment on a stomach, duodenum, bile duct, cholecyst, liver, pancreatic duct, pancreas, or the like, as a digestive organ.

Conventional guidewires for digestive organs, used with the technique of such a low incision damage, are suggested in Japanese Patent Application KOKAI Publication No. 2-180277 and U.S. Pat. No. 5,111,829, for example. Each of these guidewires has an inner core made of a superelastic metal and an X-ray contrast portion provided at the top end, and the entire of the inner core and the X-ray contrast portion is coated with a synthetic resin. The coating has a substantially uniform outer diameter and has an outer circumferential surface which is shaped into a smooth and even cylindrical surface without roughness.

However, in the guidewires described above, the outer circumferential surface of synthetic resin coating the inner core has a smooth cylindrical shape without roughness. Therefore, in case of actually guiding a catheter by the guidewire described above, the inner circumferential surface of the catheter is closely contacted on and intensively sticks to the smooth and even outer circumferential surface of the guidewire. The friction resistance when the guidewire slides is large and makes worce an operability in inserting and/or pulling out a catheter.

In this respect, Japanese Utility Model Application KOKOKU Publication No. 2-40992, Japanese Patent Application KOKAI Publication No. 62-231675, Japanese Utility Model KOKOKU Publication No. 61-7735, and U.S. Pat. No. 4,579,127 have proposed guidewires each of which has an outer circumferential surface formed in an uneven shape in order to decrease the friction resistance to a catheter or the like.

In the guidewire suggested in Japanese Utility Model Application KOKOKU Publication No. 2-40992, a tube-like member freely engaged on the inner core is formed of a net-like member or the outer circumferential surface of the tube-like member is processed by a lacquer ware with a flecked effect, so that the outer circumferential surface of the tube-like member is formed to have an uneven surface.

In the guidewire according to Japanese Patent Application KOKAI Publication No. 62-231675, a thin wire-like inner core is coated with a relatively thick coating layer, and the outer circumferential surface portion of the coating layer is formed to be uneven.

In the guidewire according to Japanese Utility Model Application KOKOKU Publication No. 61-7735, a relatively thin coating film is applied to the outer circumference of the coil-like spring composing the guidewire, such that the coating film has an uneven shape.

U.S. Pat. No. 4,579,127 suggests a catheter and a probe-mandrel, which are comprised of a wire core and an external wire wound like a coil on the wire core, and a thin resin-made coating layer of a uniform thickness is formed on the semicircular circumferential surface.

The guidewire according to Japanese Utility Model Application KOKOKU Publication No. 2-40992 is made of a tube-like member freely engaged on an inner core and has a drawback that the structure is complicated and thick. Although its thickness, its rigidity is rather low, and further, the guidewire lacks a force transmission ability when it is twisted.

In the guidewire according to Japanese Patent Application KOKAI Publication No. 62-231675, its narrow wire-like inner core is coated with a relatively thick coating layer, so that the guidewire tends to be thickened with ease. The rigidity of the guidewire is rather low in spite of its thickness. Further, the guidewire lacks a force transmission ability when it is twisted. In the guidewire according to Japanese Utility Model Application KOKOKU Publication No. 61-7735, it comprises a coil-like spring as a core member, so that the guidewire lacks rigidity and a force transmission ability when it is twisted. Further and the follow-up ability of its top end portion is low.

Further, the mandrel according to U.S. Pat. No. 4,579,127 has a structure in which an external wire is wound like a coil on the wire core, so that the guidewire has low rigidity although it has flexibility, and the guidewire lacks force transmission ability when it is twisted. In this structure, the function of guiding a catheter or the like easily tends to be affected. Also, the entire guidewire must be thickened to improve the rigidity and the transmission ability. However, such a guidewire is not preferable as a guidewire.

BRIEF SUMMARY OF THE INVENTION

The present invention has been made in view of the problems described above and has an object of providing a guidewire having a reduced diameter, which ensures rigidity and excellent guidance ability in spite of its reduced diameter, and which achieves an excellent slide ability and insertion ability with respect to a catheter or the like.

According to the present invention, there is provided a guidewire for using with a medical device having a hollow structure, comprising: an inner core formed of one of a strand formed of a plurality of wire elements without a core member and a single wire, the inner core having an outer circumferential surface having at least a part formed of an uneven surface; and a high-polymer coating having an outer circumferential surface and covering the outer circumferential surface of the inner core, the outer circumferential surface of the high-polymer coating having an uneven surface formed by the uneven surface of the outer circumferential surface of the inner core.

According to the guidewire, an uneven surface is formed on the outer circumferential surface of the coating by an influence from the unevenness of the outer circumferential surface of the inner core, and as a result, the contact portion of the guidewire with respect to a catheter or an endoscope channel is dispersed into several points. Since the contact area is thus reduced, the guidewire is prevented from sticking to the catheter or the endoscope channel. The uneven surface of the outer circumferential surface of the inner core forms the outer circumferential surface of the coating into an

uneven surface, so that the shape of the unevenness of the outer circumferential surface of the coating can be controlled finely and easily by appropriately selecting the shape of the unevenness of the outer circumferential surface of the inner core.

Therefore, the inner core of the guidewire according to the present invention is formed of a single wire or a strand without a core member. The inner core is coated with a coating and the uneven shape formed on the outer circumference of the inner core appears on the outer circumference of the coating. Accordingly, regardless of a coating having an uneven outer circumferential surface, the thickness of the coating is thinned in comparison with the thickness of the inner core, and the guidewire is very thin and attains high rigidity. At the same time, the ability of transmitting a force required for operation is excellent when the guidewire is twisted, and the follow-up ability of the distal end of the guidewire is also excellent.

As has been described above, according to the present invention, the contact portion in contact with a catheter, an endoscope channel, or the like is dispersed into several points, by the uneven shape of the outer circumferential surface of the coating caused by the uneven shape of the outer circumferential surface of the inner core of the guide wire. In this manner, the contact area of the contact points is decreased to prevent the guidewire from sticking to the catheter or the endoscope channel. Therefore, the guidewire can be smoothly slid by a slight force, so that the guidewire can be smoothly inserted or pulled out.

In addition, since the uneven shape of the outer circumferential surface of the coating is shaped along the uneven shape of the outer circumferential surface of the inner core, the outer circumferential surface of the coating can be easily controlled by appropriately selecting the outer circumferential shape of the inner core. Accordingly, the shape of the outer circumferential surface of the fine coating can be easily created.

Further, since the uneven shape formed on the outer circumferential surface of the inner core is arranged so as to appear on the outer circumferential surface of the coating, the thickness of the coating can be reduced in comparison with the thickness of the inner core even though the outer circumferential surface of the coating has an uneven shape. Accordingly, it is possible to provide a guidewire which is very thin and has excellent rigidity. When the guidewire is twisted, the ability of transmitting a force, which is necessary for operation, is excellent, and the distal end portion of the guidewire has an excellent follow-up ability.

Preferably, the inner core has an elongated and thin main body portion at least a part of which is made of metal having a superelastic characteristic, a distal end portion extending from the main body portion and having a smaller diameter than the main body portion, and a high X-ray contrast portion provided at the distal end portion.

In addition, the outer circumferential surface of the inner core preferably has at least one of a spiral groove and a spiral projection, extending along a longitudinal axis of the inner core.

At least a part of the inner core preferably has a superelastic characteristic.

Further, the high X-ray contrast portion contains any metal selected from a group of gold, silver, platinum, tungsten, bismuth oxide, palladium, and tantalum, as a main component.

The high X-ray contrast portion preferably includes one of a coil-like shape and a pipe-like shape.

At least a part of the high-polymer coating is preferably made of a material selected from a group of fluorine-based resin, polyethylene, polyester, polypropylene, polyamide, polyurethane, polystyrene, elastomer thereof, polyvinyl chloride, and silicon rubber.

The high-polymer coating preferably has a lubrication layer on the outer circumferential surface, and the lubrication layer preferably includes a lubrication material applied onto a portion of the outer circumferential surface of the high-polymer coating.

Further, the guidewire can preferably be used for digestive organs.

Additional objects and advantages of the invention will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention may be realized and obtained by means of the instrumentalities and combinations particularly pointed out hereinafter.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING

The accompanying drawings, which are incorporated in and constitute a part of the specification, illustrate presently preferred embodiments of the invention, and together with the general description given above and the detailed description of the preferred embodiments give below, serve to explain the principles of the invention.

FIGS. **1A** and **1B** are respectively longitudinal and transversal cross-sectional views showing a medical guidewire according to a first embodiment of the present invention.

FIGS. **2A** and **2B** are longitudinal and transversal cross-sectional views showing a medical guidewire according to a second embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[First Embodiment]

FIGS. **1A** and **1B** show a medical guidewire according to a first embodiment of the present invention.

(Structure)

The guidewire **1** integrally consists of an inner core **2** formed of a single wire having an elasticity, and a coating **3** made of synthetic resin (of high-polymer or high-molecular weight compound) which covers substantially the entire of the inner core **2**. The guidewire **1** according to the present embodiment has, for example, an outer diameter of about 0.2 to 0.8 mm and an overall length of about 2 to 3 meter, and is formed as a guidewire for a digestive organ, which is useful when used together with a duodenum drainage tube or an endoscope, for example.

The inner core **2** is made of an integral member comprising of a main body portion **4** which is relatively thick and rigid, and a distal end portion **5** which has a smaller diameter than the main body portion **4** and is tapered to be gradually thinned. The inner core **2** is made of an elastic material, e.g., pseudoelastic metal such as SUS or the like, or is made of superelastic metal or the like containing nickel and titanium as its main components. Superelastic alloy containing nickel and titanium as main components is suitable for the inner core **2**. In addition, only the portion in the side of the top end, which requires a sufficient elasticity, may be formed of superelastic metal.

A groove **6** or a projection which extends spirally along the axial direction is formed on the outer circumference of

the inner core **2**. Specifically, like stranded wires as shown in a second embodiment described later, the groove or projection is formed in the same uneven shape of the outer circumferential surface as will be obtained where three wires are stranded together. Naturally, the groove **6** or the projection may have a different shape other than a spiral shape. Also, the groove **6** or the projection may have an appropriate cross-sectional shape other than the shape defined by curves as shown in FIG. 1B.

A high X-ray contrast portion **7** is provided at the front end portion of the distal end portion **5** of the inner core **2**. The high X-ray contrast portion **7** is coated with a coating **3**. The high X-ray contrast portion **7** is, for example, a thin wire wound like a coil or a film-like portion having a cylindrical shape. The material of the portion **7** may be gold, silver, platinum, tungsten, bismuth oxide, palladium, tantalum, or alloy containing any of them as its main component, or may preferably be platinum.

The outer circumferential surface of the inner core **2** is coated densely with a coating **3** having a uniform thickness, and the coating **3** is coated to be fitted tightly on the outer circumferential surface of the inner core **2**, and an undulatory uneven surface **8** which corresponds to the shape of the outer circumferential surface of the inner core **2** defines the outer circumferential surface of the coating **3**. The uneven portion **8** formed on the outer circumferential surface of the coating **3** may be provided entirely over the coating **3** or may be provided only at the portion where a high resistance will be generated when inserting and pulling out the guidewire.

The material of the coating **3** may preferably be synthetic resin or particularly be fluorine-based resin such as PTFE or the like. However, another resin material (e.g., polyethylene, polyester, polypropylene, polyamide, polyurethane, polystyrene, elastomer thereof, or elastomer containing polyvinyl chloride, silicon rubber, or the like) may be used.

The coating **3** on the outer circumferential surface of the inner core **2** may be applied by dipping or application, or may be formed by thermally shrinking the tube made of thermally shrinkable resin and fitted on the inner core **2**. The shape of the uneven surface **8** appearing on the outer circumferential surface of the coating **3** (e.g., the depth and/or pitch of its groove(s)) can be easily controlled by the shape of the outer circumferential surface of the inner core **2**.

In the present embodiment, a thin lubrication layer **9** is provided on the entire or a part of the outer circumferential surface of the coating **3**. The lubrication layer **9** may be formed of a lubrication material such as a silicon oil or the like applied on the surface, or a hydrophilic material (which is preferably polyvinyl alcohol, polyvinyl pyrolidone, or the like) upon necessity.

(Operation and advantages)

For example, when a catheter is actually guided by the guide wire **1**, the contact area in contact with inner surfaces of the catheter or an endoscope channel is reduced with the uneven surface **8** on the outer circumferential surface of a coating **3** coated on the outer circumferential surface of the inner core **2**, to prevent the guidewire from sticking to the inner surface of the catheter or endoscope channel. Both the guidewire and the catheter are smoothly slid with a slight force to facilitate guidance of the catheter and insertion into the endoscope channel. The surface of the coating of the present invention facilitates the insertion and withdrawal of the guide wire **1** easier as compared with a conventional guidewire having a even surface of synthetic resin.

Specifically, the outer circumferential surface of the guidewire **1** according to the present invention has an uneven shape, so that the contact portion in contact with the inner surface of the catheter, the endoscope channel, or the like is dispersed to several points on the uneven shape of the outer circumferential surface of the guidewire when the guidewire **1** is inserted into a catheter, a digestive organ, or an endoscope channel. Therefore, the guidewire **1** slides more excellently than the conventional guidewire having a smooth and even surface and the guidewire **1** can be smoothly inserted and pulled out.

Also, in the guidewire **1** according to the present embodiment, a coating **3** is coated on an inner core **2** composed of a single wire, and the shape of a spiral groove **6** or a projection formed on the outer circumferential surface of the inner core **2** is arranged so as to appear on the outer circumferential surface of the coating **3**. Therefore, in spite of a coating **3** which forms a fine uneven surface **8** on the outer circumferential surface, the coating **3** can be thinned in comparison with the thickness of the inner core **2** of the guidewire **1**. As a result, it is possible to provide a guidewire **1** having an excellent recovery ability and high rigidity even if the guidewire is very thin. In addition, since the inner core **2** comprises a single wire, the guidewire has an excellent transmission ability when the guidewire is twisted, and the distal end portion of the guidewire also has an excellent follow-up ability.

Further, the guidewire **1** slides in a catheter, an endoscope channel, or the like and can be smoothly inserted or pulled out. Therefore, the guidewire **1** can be used for a catheter having an inner diameter much closer to the outer diameter of the guidewire **1**.

The shape of the uneven surface **8** formed on the outer circumferential surface of the guidewire **1** can be easily controlled by appropriately selecting the shape of the outer circumferential surface of the inner core **2**, so that even a fine outer circumferential shape can be easily formed.

In the present embodiment, the guidewire **1** according to the present embodiment can be used in a situation in which it is not possible to insert and pull out a conventional guidewire, by providing a lubricity for the outer circumferential surface of the coating of the guidewire **1**.

[Second Embodiment]

FIGS. **2A** and **2B** show a medical guidewire according to a second embodiment of the present invention.

(Structure)

The guidewire **11** according to the second embodiment has an inner core **12** composed of a strand without a core member, and the strand has three wires or wire elements stranded together. Each of wires **13** of the inner core **12** is made of an elastic material, e.g., pseudoelastic metal such as SUS or the like, or superelastic metal or the like containing nickel and titanium as its main components. Also, superelastic metal containing nickel and titanium as its main components is preferably used for the wires **13**. Of course, at least the portions of the wires **13** at the distal end portions that require a sufficient elasticity may be made of superelastic metal. The other components of the structure are the same as those of the guidewire **1** according to the first embodiment described above.

(Operation and Advantages)

In the guidewire **11** according to the second embodiment, the inner core **12** is formed of the strand without a core member, so that the inner core **12** can be formed to be very thin and it is possible to provide a guidewire **11** having an excellent flexibility, an excellent kink-resistance, an excellent recover ability, and a high rigidity. In addition, since the

inner core **12** is formed of a strand without a core member, the transmission ability, which is required during operation, when the guidewire **11** is twisted is more excellent than in the case in which the coiled wire is used for the inner core. Accordingly, the follow-up ability of the distal end portion of the guidewire is improved. In addition, even if the wires **13** of the inner core **12** are made of SUS or the like, it is possible to obtain substantially the same torque transmission ability as in the case where the inner core **12** made of single wire **13** is made of superelastic metal.

In addition, it is possible to achieve the same operation and advantages as those obtained in the second embodiment described above.

The wires **13** of the inner core **12** according to the present embodiment may be constructed by combining wires **13** made of different materials, having different diameters, or having different cross-sectional shapes. Also, the guidewire according to the present invention includes a medical guidewire used for circulatory organs other than digestive organs.

Additional advantages and modifications will readily occurs to those skilled in the art. Therefore, the invention in its broader aspects is not limited to the specific details and representative embodiments shown and described herein. Accordingly, various modifications may be made without departing from the spirit or scope of the general inventive concept as defined by the appended claims and their equivalents.

What is claimed is:

1. A guidewire for use with a medical device having a hollow structure, comprising:

an inner core selected from the group consisting of

(a) a strand formed of a plurality of wire elements without a core member, and

(b) a single wire; the inner core having an outer circumferentially uneven surface having; and

a high-polymer coating having an outer circumferential surface and covering the outer circumferential surface of the inner core, the outer circumferential surface of the high-polymer coating having an uneven surface formed by the uneven surface of the outer circumferential surface of the inner core the uneven surface dispersing contact points for the guidewire to provide excellent slideability with respect to the medical device.

2. A guidewire according to claim **1**, wherein the inner core has an elongated thin main body portion at least a part of which is made of metal having a superelastic characteristic, a distal end portion extending from the main body portion and having a diameter smaller than that of the main body portion, and a high X-ray contrast portion provided at the distal end portion.

3. A guidewire according to claim **1**, wherein the outer circumferential surface of the inner core has at least one selected from the group consisting of a spiral groove and a spiral projection, extending along a longitudinal axis of the inner core to form the uneven surface.

4. A guidewire according to claim **1**, wherein at least a part of the inner core has a superelastic characteristic.

5. A guidewire according to claim **2**, wherein the high X-ray contrast portion contains any metal selected from the group consisting of gold, silver, platinum, tungsten, bismuth oxide, palladium, and tantalum, as a main component.

6. A guidewire according to claim **2**, wherein the high X-ray contrast portion includes one selected from the group consisting of a coil-like shape and a pipe-like shape.

7. A guidewire according to claim **1**, wherein at least a part of the high-polymer coating is made of a material selected from the group consisting of fluorine-based resin, polyethylene, polyester, polypropylene, polyamide, polyurethane, polystyrene, elastomer thereof, polyvinyl chloride, and silicon rubber.

8. A guidewire according to claim **1**, wherein the high-polymer coating has a lubrication layer on the outer circumferential surface.

9. A guidewire according to claim **8**, wherein the lubrication layer includes a lubrication material applied onto a portion of the outer circumferential surface of the high-polymer coating.

10. A guidewire according to claim **1**, wherein the guidewire is applicable for digestive organs.

11. A guidewire for use with a medical device having a hollow structure, comprising:

an inner core selected from the group consisting of

(a) a strand formed of a plurality of wire elements without a core member, and

(b) a single wire; the inner core having an outer circumferentially uneven surface; and

a high-polymer coating having an outer circumferential surface and covering the outer circumferential surface of the inner core, the outer circumferential surface of the high-polymer coating having an uneven surface formed by the uneven surface of the outer circumferential surface of the inner core; and

wherein at least a part of the inner core has a superelastic characteristic.

12. A guidewire according to claim **11**, wherein the said at least a part of the inner core with a superelastic characteristic has an elongated thin main body portion at least a part of which is made of metal having a superelastic characteristic, the elongated thin metal body portion having a distal end portion extending from the main body portion and having a diameter smaller than that of the main body portion, and a high X-ray contrast portion provided at the distal end portion.

13. A guidewire according to claim **12**, wherein the high X-ray contrast portion contains a metal selected from the group consisting of gold, silver, platinum, tungsten, bismuth oxide, palladium, and tantalum, as a main component.

14. A guidewire according to claim **12**, wherein the high X-ray contrast portion includes one selected from the group consisting of a coil-like shape and a pipe-like shape.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,251,085 B1
APPLICATION NO. : 09/103368
DATED : June 26, 2001
INVENTOR(S) : Toshiaki Tezuka

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page, under "References Cited, U.S. Patent Documents", after "5, 769,796" line 5 delete "6/1999" and replace with - -6/1998 - -.

Column 7, (claim 1), lines 33 to 37 delete

"an inner core selected from the group consisting of
(a) a strand formed of a plurality of wire elements without a core member, and
(b) a single wire; the inner core having an outer circumferentially uneven surface; and"

and replace with:

--an inner core formed of a single wire; the inner core having an outer circumferentially uneven surface; and - -

Column 8, (claim 11), lines 27-31 delete

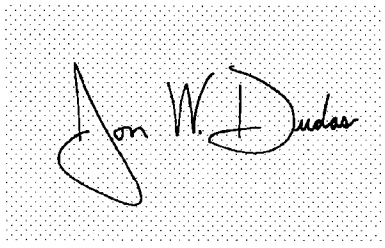
"an inner core selected from the group consisting of
(a) a strand formed of a plurality of wire elements without a core member, and
(b) a single wire; the inner core having an outer circumferentially uneven surface; and"

and replace with:

--an inner core formed of a single wire; the inner core having an outer circumferentially uneven surface; and - -

Signed and Sealed this

Twenty-second Day of August, 2006



JON W. DUDAS
Director of the United States Patent and Trademark Office

EXHIBIT 6

US005228453A

United States Patent [19]

Sepetka

[11] Patent Number: 5,228,453

[45] Date of Patent: Jul. 20, 1993

[54] **CATHETER GUIDE WIRE**

[75] Inventor: **Ivan Sepetka**, Redwood City, Calif.

[73] Assignee: **Target Therapeutics, Inc.**, Fremont, Calif.

[21] Appl. No.: **952,206**

[22] Filed: **Sep. 28, 1992**

Related U.S. Application Data

[63] Continuation of Ser. No. 696,585, May 7, 1991, abandoned.

[51] **Int. Cl.**[5] **A61B 5/00**

[52] **U.S. Cl.** **128/772**; 128/657

[58] **Field of Search** 128/657, 772; 604/95, 604/164, 285

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,003,369	1/1977	Heilman et al.	128/772
4,719,924	1/1988	Crittenden et al.	128/657
4,884,579	12/1989	Engelson	128/657
4,922,924	5/1990	Gambale et al.	128/657
4,964,409	10/1990	Tremulis	128/657
5,065,769	11/1991	de Toledo	128/772
5,069,217	12/1991	Fleishhacker	128/772
5.129,890	7/1992	Bates et al.	128/772

Primary Examiner—Max Hindenburg
Attorney, Agent, or Firm—Morrison & Foerster

[57] **ABSTRACT**

A catheter guide wire comprising: a flexible, torqueable proximal wire section, a more flexible intermediate section with a flexible polymer tube covering, and a most flexible distal end section. A helical ribbon coil is wrapped about the intermediate core segment between the wire core and the polymer tube covering to increase radiopacity and improve torque transmission while retaining flexibility.

8 Claims, 1 Drawing Sheet

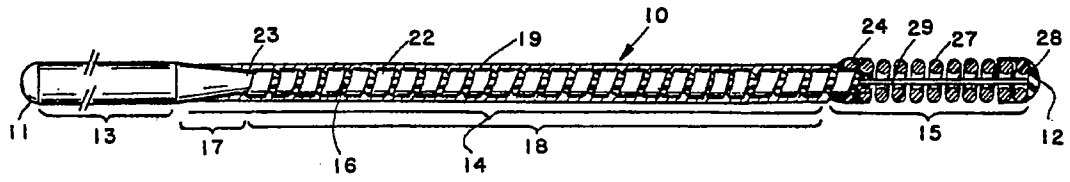


EXHIBIT 6

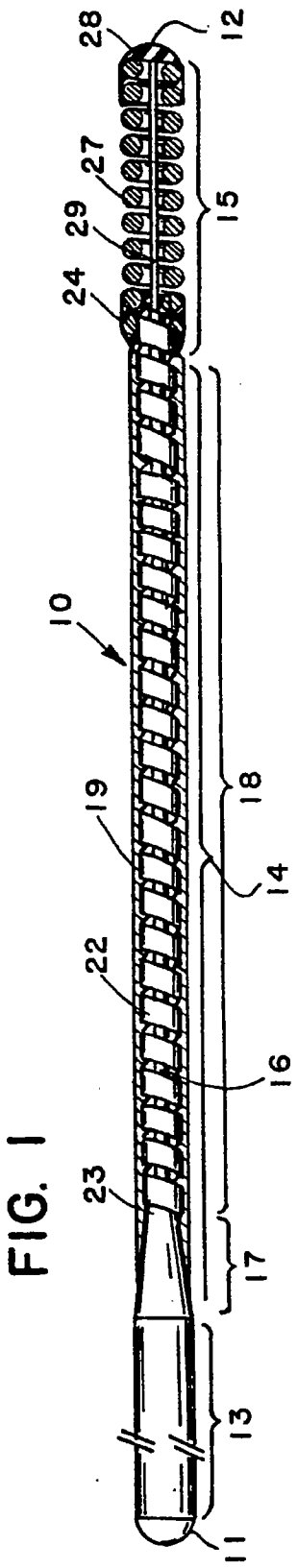

28
12
27
29
15
24
10
19
18
14
22
16
23
17
13
11

FIG. 1

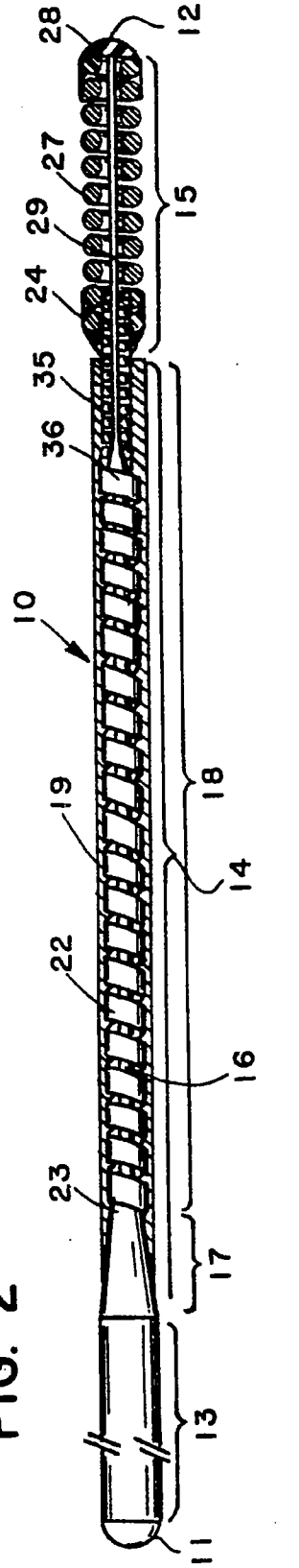

28
12
27
29
15
24
35
36
10
19
18
14
22
16
23
17
13
11

FIG. 2

CATHETER GUIDE WIRE

This application is a continuation of application Ser. No. 07/696,585, filed May 7, 1991, now abandoned.

DESCRIPTION

1. Technical Field

This invention is in the general field of surgical instruments and relates specifically to guide wires that are used in cardiovascular and endovascular procedures to facilitate the placement of catheters within the vasculature of patients.

2. Background

The general procedure for placing catheters within vessels is to track a guide wire through the vessel to the desired position and advance the catheter over the guide wire. Guide wires are required because the catheters themselves do not have sufficient column strength or torsional strength to be able to be tracked or steered through the vessel. See, for instance, U.S. Pat. No. 4,884,579.

Several types of guide wires for use in catheter placement have been proposed. The simplest type of wire has a preferred diameter of between about 0.20–1.0 mm. The distal end of the wire may be provided with a bent tip which can be oriented, by means of a guide structure at the proximal end, to guide the wire along a selected vascular path. Ideally, torque transmission should be controlled, such that a selected wire rotation at the wire's proximal end produces a corresponding rotation of the distal end. Further, radiopacity is desired such that a physician may see over the entire vasculature accessed by the guide wire.

The present invention is an improvement on the guide wire assembly described in U.S. Pat. No. 4,884,579. The prior invention describes a catheter guide wire with three sections with progressively greater flexibility and sliding properties: 1. A semi-rigid, torqueable proximal wire section that is between about 50–250 cm in length, formed of a proximal wire core segment having an outer diameter of between about 0.25–1.0 mm; 2. A more flexible intermediate section that has a length between about 20–60 cm and is formed from an intermediate wire-core segment having a reduced diameter of between about 0.10–0.50 mm, and a low-friction, flexible polymer tube covering which encases the intermediate core segment; and 3. A most distal end section with a length between about 1–10 cm and formed from a distal wire core segment having a reduced diameter of between about 0.05–0.15 mm, and a flexible sleeve covering the distal end segment and providing column strength thereto.

A primary object of the present invention is the improvement of the torque transmission and radiopacity of the above described invention.

DISCLOSURE OF THE INVENTION

The invention is an improvement to U.S. Pat. No. 4,884,579 which describes a catheter guide wire for use within a patient's vasculature comprising in combination:

(a) a flexible, torqueable proximal wire section,

(b) a more flexible intermediate section formed from an intermediate wire-core segment having a flexible polymer tube covering which encases the intermediate core segment, and

(c) a most flexible distal end section formed from a distal wire core segment with a helical coil covering the distal end segment and providing column strength thereto.

The improvement comprises a radiopaque helical ribbon coil wrapped about the intermediate core segment between the intermediate wire core and the flexible polymer tube covering. This improvement serves to increase radiopacity and improve torque transmission while retaining flexibility.

BRIEF DESCRIPTION OF THE DRAWING

In the drawing:

FIG. **1** shows fragmentary portions of a guide wire constructed according to one embodiment of the invention.

FIG. **2** shows fragmentary portions of a guide wire constructed according to another embodiment of the invention.

Like parts are referred to by the same reference numerals in the figures.

MODES FOR CARRYING OUT THE INVENTION

FIG. **1** shows a guide wire generally designated **10**, constructed according to one embodiment of the invention. The wire is a flexible torqueable wire having an overall length of about 70–300 cm between its proximal and distal ends **11** and **12**, respectively, and a maximum outer diameter of between about 0.20–1.0 mm. The major portion of the wire is a flexible proximal section **13** whose overall length ranges from about 50–250 cm. This section is followed by a more flexible intermediate section **14** having a length between about 20–60 cm and a most flexible distal end section **15** whose length is between about 1–10 cm.

A wire core **16** in the guide wire **10** is formed of a flexible, torqueable wire filament material, such as stainless steel. The diameter of the wire core, at its maximum, is between about 0.20–1.0 mm. The segment of the core forming proximal section **13** of guide wire **10** has a substantially uniform diameter along its length, and corresponds to the maximum diameter of the core, i.e., between 0.20–1.0 mm.

Within the intermediate section **14** of the wire, the core is tapered from the proximal-section diameter down to a reduced diameter which is preferably about 0.10–0.50 mm and between about 10%–50% of the diameter of the core's proximal segment **13**. Thus, for example, where the proximal section core diameter is 0.46 mm, the core tapers to a minimum of between about 0.05–0.23 mm. The length of tapered segment **17** is typically between about 10%–50% that of reduced-diameter segment **18**, and the two segments together make up the length of the intermediate wire section **14**, i.e., about 20–60 cm.

The wire core **16** of intermediate section **14** is covered along its length by a flexible polymer covering **19**. The major function of covering **19** is to provide a low-friction surface along intermediate section **14**, and more particularly, a surface which has less friction than the surface of adjacent distal segment **15** and proximal segment **13** (the wire core itself). Covering **19** preferably also functions to provide column support to the reduced-diameter core of the intermediate section, **18**, to reduce the tendency of this section to buckle under axial compression.

Covering **19** is preferably formed of a polymer, such as TEFLON TM, polyolefin, or polyurethane which can be bonded or otherwise tightly affixed to the core wire, and which itself has a low-friction surface, or can be coated with a low-friction surface. Other suitable coverings include a tube formed from virtually any polymer having exposed hydrogens, such as polyester, polyolefins, polycarbonate, polyvinylchloride, latex or silicon rubber, polystyrene, and polyacrylics, and a surface coating formed of a highly hydrophilic, low-friction polymer, such as polyvinylpyrrolidone (PVP), polyethyleneoxide, or polyhydroxyethylmethacrylate (polyHEMA) or copolymers thereof.

Beneath polymer covering **19**, a ribbon of radiopaque metal **22**, such as platinum, gold, tungsten, or their alloys is wound around the wire core **16**. As shown, the ribbon coil **22** extends from tapered segment **17** of intermediate section **14** at junction **23**, to the distal junction **24** of intermediate section **14**. The ribbon coil **22** has a thickness of about 0.015 to 0.050 mm, preferably about 0.025 mm and a width of about 0.050 to 0.130 mm, preferably about 0.075 mm. There are approximately 5 to 15 complete turns of ribbon per millimeter of wire core, and preferably about 10 complete turns of ribbon per millimeter of wire core.

The distal section **15** of guide wire **10** is fully or partially encased in flexible sleeve **27**. Sleeve **27** shown in FIG. **1** is a soft, flexible helical coil which is formed conventionally, e.g., as a winding of radiopaque wire strand, such as platinum, gold, or tungsten strand. The wire strand has a diameter of about 0.050 to 0.100 mm and preferably about 0.075 mm. As shown, sleeve **27** extends from junction **24** to distal end **12** of guide wire **10**. Attachment of the sleeve **27** to wire core **16** is preferably by two or three solder or weld joints, one at proximal junction **24** and a second at rounded distal junction **28**.

In addition to providing a mechanism for wire bending near wire tip **12**, sleeve **27** also gives distal section **15** of guide wire **10** increased column strength (in the axial direction), and reduces the chance of buckling in this section with axial compression. At the same time, the combined flexibility of reduced diameter core **29** and sleeve **27** are compatible with a series of sharp bends, as the wire is moved through a patient's vasculature. Rounded joint **28** at the end of guide wire **10** acts to shield vessel walls from the sharp end of wire core **16**. Further, the distal section of the wire, **15**, with the associated sleeve **27**, provides the section with a higher frictional coefficient than that of the adjacent intermediate section, **14**. The higher-friction surface in this distal section, **15**, functions specifically, during a catheter placement operation, to help anchor distal section **15** against a vessel wall at a vessel junction.

Distal wire core **29** has a substantially uniform cross-section. The core may be cylindrical with diameter of between 0.05 and 0.15 mm or flattened with a rectangular cross-section dimensioned 0.025 mm by 0.075 mm. The wire core has a tapered section at junction **24** that covers between about 10–50% of the core's distal segment.

FIG. **2** is another embodiment of the invention that is essentially the same as FIG. **1** except for the replacement of a portion of helical ribbon coil **22** with inner wire coil **35**. At the distal end of helical ribbon coil **22**, there is a soft flexible helical coil **24** which is formed conventionally, e.g., as a winding of radiopaque wire strand, such as platinum, gold or tungsten. As shown, coil **35** extends from helical ribbon coil **22** at junction **36** to the proximal end of distal segment **15** at junction **24**. This inner coil **35** serves as an anchor point for the distal end of flexible helical coil **22** and also as an anchor point for the polymer covering **19** on intermediate core section **14**.

I claim:

1. In a catheter guide wire for use within a patient's vasculature comprising in combination:

(a) a semi-rigid, torqueable proximal wire section,

(b) a more flexible intermediate section formed from an intermediate wire-core segment having a flexible polymer tube covering which encases the intermediate core segment, and

(c) a most flexible distal end section formed from a distal wire core segment with a helical coil covering the distal end segment and providing column strength thereto,

the improvement comprising a radiopaque helical ribbon coil wrapped about the intermediate core segment between the intermediate core segment and the flexible polymer tube covering so to improve torque transmission and increase radiopacity of the intermediate section over that of the bare intermediate core segment without substantially increasing its stiffness.

2. The guide wire of claim **1** wherein the ribbon coil is formed from a radiopaque metal selected from the group consisting of platinum, gold, tungsten and their alloys.

3. The guide wire of claim **1** wherein the ribbon coil is a tightly wound coil with a thickness of about 0.015 to 0.050 mm and a width of about 0.050 to 0.130 mm, which extends from the proximal wire section of the guide wire to the junction of the distal wire core segment.

4. The guide wire of claim **1** wherein:

(a) the flexible, torqueable proximal wire section has an outer diameter of between about 0.25–0.10 mm, and

(b) the intermediate wire core segment has a reduced diameter of between about 0.10–0.50 mm, and

(c) the distal wire core segment has a reduced cross-sectional area.

5. The guide wire of claim **4** wherein the distal wire core segment is cylindrical and has a diameter of between about 0.05 and 0.15 mm.

6. The guide wire of claim **4** wherein the distal wire core segment is rectangular with cross-sectional dimensions of 0.025 mm by 0.075 mm.

7. The guide wire of claim **1** wherein:

(a) the flexible, torqueable proximal wire section has an outer diameter of between about 0.25–0.50 mm, and

(b) the intermediate wire core segment has a reduced diameter of between about 0.10–0.20 mm, and

(c) the distal wire core segment has a reduced diameter of between about 0.05–0.13 mm.

8. In a catheter guide wire for use within a patient's vasculature comprising in combination:

(a) a flexible, torqueable proximal wire section,

(b) a more flexible intermediate section formed from an intermediate wire-core segment having a flexible polymer tube covering which encases the intermediate core segment, and

(c) a most flexible distal end section formed from a distal wire core segment with a helical coil cover-

ing the distal end segment and providing column strength thereto,

the improvement comprising a radiopaque helical ribbon coil wrapped about the intermediate core segment between the intermediate core segment and the flexible polymer tube covering so to improve torque transmission and increase radiopacity of the intermediate section over that of the bare intermediate core segment without substantially increasing its stiffness and wherein a platinum helical coil wrapped around the proximal end of the distal section serves as an anchor point for the proximal end of the distal helical coil and the anchor point for the distal end of the flexible polymer tube covering which encases the intermediate core segment and the helical ribbon coil.

* * * * *

EXHIBIT 7

US005443907A

United States Patent [19]

Slaikeu et al.

[11] Patent Number: 5,443,907

[45] Date of Patent: Aug. 22, 1995

[54] **COATING FOR MEDICAL INSERTION GUIDES**

[75] Inventors: **Paul Slaikeu**, Vadnais Heights; **Paul H. Burmeister**, White Bear Lake; **Richard E. Cappetta**, Plymouth; **Steven S. Hackett**, Minnetonka, all of Minn.

[73] Assignee: **Scimed Life Systems, Inc.**, Maple Grove, Minn.

[21] Appl. No.: **350,714**

[22] Filed: **Dec. 7, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 25,720, Mar. 2, 1993, abandoned, which is a continuation of Ser. No. 799,449, Nov. 27, 1991, abandoned, which is a continuation-in-part of Ser. No. 716,678, Jun. 18, 1991, abandoned.

[51] **Int. Cl.**[6] **D02G 3/00**

[52] **U.S. Cl.** **428/375**; 428/394; 428/395; 604/172; 604/165; 128/657; 128/772

[58] **Field of Search** 428/375, 394, 395; 604/172, 165; 128/657, 772

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,216,983	11/1965	Shelanski	260/88.3
3,661,634	5/1972	Riley et al.	117/161 UA
3,695,921	10/1972	Shepherd et al.	117/72
3,861,396	1/1975	Vaillancourt et al.	128/350 R
3,896,753	7/1975	Shepherd et al.	114/67 R
3,939,049	2/1976	Ratner et al.	204/159.13
4,055,682	10/1977	Merrill	427/2
4,087,567	5/1978	Sullivan	427/2
4,100,309	7/1978	Micklus et al.	427/2
4,112,925	9/1978	Sullivan	128/2 F
4,119,094	10/1978	Micklus et al.	128/132 R
4,143,423	3/1979	Sternlieb	2/168
4,169,163	9/1979	Judd et al.	426/413
4,239,664	12/1980	Teng et al.	260/17.4 R
4,345,602	8/1982	Yoshimura et al.	128/349
4,373,009	2/1983	Winn	428/424.2
4,381,008	4/1983	Thomas et al.	604/265
4,384,954	5/1983	Nakashima et al.	210/287
4,456,017	6/1984	Miles	128/772
4,459,317	7/1984	Lambert	427/2
4,482,577	11/1984	Goldstein et al.	427/2
4,487,808	12/1984	Lambert	428/423.1
4,534,363	8/1985	Gold	128/772
4,557,724	12/1985	Gregonis et al.	604/49
4,585,666	4/1986	Lambert	427/2
4,589,873	5/1986	Schwartz et al.	604/265
4,642,267	2/1987	Creasy et al.	428/413
4,666,437	5/1987	Lambert	523/113
4,682,607	7/1987	Vaillancourt et al.	128/772
4,721,117	1/1988	Mar et al.	128/772

FOREIGN PATENT DOCUMENTS

0340304	11/1989	European Pat. Off. .
0380102	8/1990	European Pat. Off. .
0405823	1/1991	European Pat. Off. .
0407965	1/1991	European Pat. Off. .
83118796	1/1985	Japan .
88334359	7/1990	Japan .
1600963	10/1981	United Kingdom .
WO85/01444	4/1985	WIPO .
WO89/09626	10/1989	WIPO .

Primary Examiner—N. Edwards

Attorney, Agent, or Firm—Vidas, Arrett & Steinkraus

[57] **ABSTRACT**

An improved guide for a medical insertion device includes a core, a jacket of hydrophobic polymer surrounding the core, and a mixture of hydrophobic and hydrophilic polymer coated onto the jacket. The hydrophobic polymer of the coating is the same as or compatible with the hydrophobic polymer of the jacket, resulting in improved bonding between the jacket and coating. The hydrophilic polymer of the coating provides a slippery surface which facilitates insertion of the device into a vein or other organ. The hydrophilic polymer has reduced tendency to leach or dissolve away, because it is ensnared with the hydrophobic polymer of the coating.

(List continued on next page.)

9 Claims, 1 Drawing Sheet

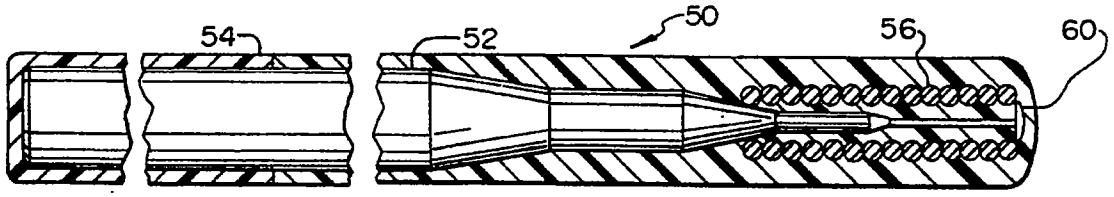


EXHIBIT 7

U.S. PATENT DOCUMENTS

4,729,914	3/1988	Kliment et al.	428/36
4,739,768	4/1988	Elgelson	128/655
4,758,475	7/1988	Eckes et al.	428/423.1
4,769,013	9/1988	Lorenz et al.	604/265
4,781,703	11/1988	Walker et al.	604/264
4,811,743	3/1989	Stevens	128/772
4,835,003	5/1989	Becker et al.	427/2
4,841,976	6/1989	Packard et al.	128/657
4,867,174	9/1989	Skribiski	128/772
4,872,867	10/1989	Joh	604/269
4,883,699	11/1989	Aniuk et al.	428/36.9
4,884,579	12/1989	Engelson	128/772
4,899,787	2/1990	Ouchie et al.	138/131
4,906,237	3/1990	Johansson et al.	604/265
4,925,445	5/1990	Sakamoto et al.	604/95
4,950,257	8/1990	Hibb et al.	604/265
4,955,862	9/1990	Sepetka	604/164
4,961,731	10/1990	Bodicky et al.	604/264
4,977,901	12/1990	Ofstead	128/772
4,990,357	2/1991	Karakelle et al.	427/2
4,991,602	2/1991	Amplatz et al.	128/772
5,001,009	3/1991	Whitbourne	428/412
5,041,100	8/1991	Rowland et al.	604/265
5,047,045	9/1991	Arney et al.	606/144
5,061,254	10/1991	Karakelle et al.	604/265
5,069,226	12/1991	Yamauchi et al.	128/772
5,084,315	1/1992	Karimi et al.	428/36.6

OTHER PUBLICATIONS

Klempner, "Interprenetrating Polymer Networks", Angew. Chem. Int. Ed. Engl. 17, 97–106 (1978).

Hunter et al., "Surface Modification Of Polyurethane To Promote Long-Term Potency Of Peritonecal Access Devices", Trans. Am. Soff. Intern. Organs, vol. XXIX, 250–254 (1983).

Moore, et al.—"Endovascular Surgery", W. B. Saunders Co. (1989), pp. 157–159.

"Cordis Ducor And The Angiographic System", Cordis Corp. (1973).

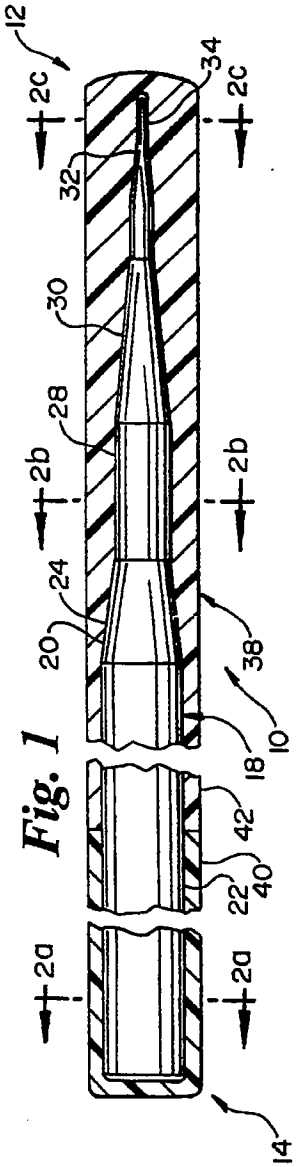


Fig. 1

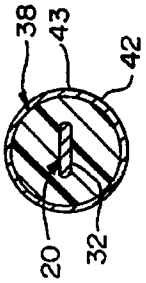


Fig. 2c

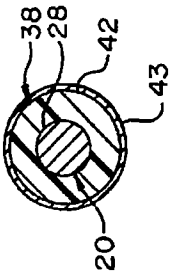


Fig. 2b

Fig. 2a

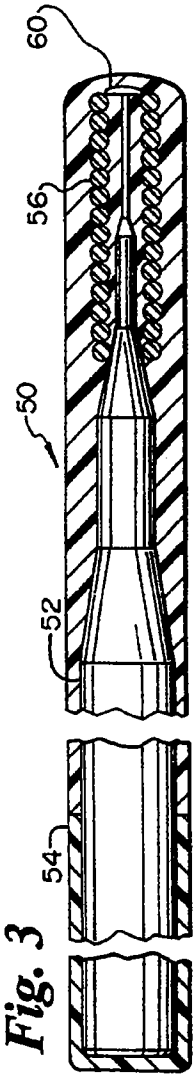


Fig. 3

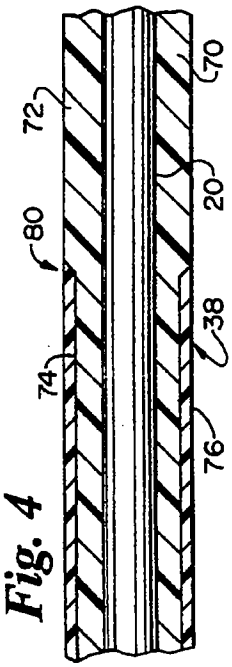


Fig. 4

COATING FOR MEDICAL INSERTION GUIDES

RELATED APPLICATIONS

This is a continuation of application Ser. No. 08/025,720, filed on Mar. 2, 1993, now abandoned, which is a continuation of application Ser. No. 07/799,449, filed Nov. 27, 1992, now abandoned, which is a continuation-in-part of U.S. application Ser. No. 07/716,678, filed on Jun. 18, 1991, is now abandoned, the entire disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

This invention relates to an improved jacket and coating combination for the guide portions of medical insertion devices such as catheters, probes, guide wires, pacemakers and other devices, which are inserted into the human body for various medical purposes.

BACKGROUND OF THE INVENTION

There is a need in the field of medical insertion devices to provide a slippery yet medically safe surface so that the device can easily be inserted into the human body without causing injury, infection, or excessive discomfort. Usually, the medical insertion device has a guide portion which is inserted into the body first, and whose surface should be exceptionally slippery when wet. The guide portion surface must minimize friction between the guide portion and the inside of the vein or organ, and must also be non-toxic and otherwise chemically inert when exposed to bodily fluids.

Various means for minimizing the surface friction of the guide portions of medical devices are known. U.S. Pat. No. 5,835,003 issued to Becker et al., discloses a medical tubing whose exterior is at least partially covered with a water-activated lubricating coating of a hydrophilic (i.e. water absorbing) thermoplastic resin which is adhesively compatible with the material of the medical tubing. The reference specifically discloses the use of a thermoplastic hydrophilic polyurethane resin. A quantity of polyvinyl pyrrolidone having a molecular weight of at least 200,000 is intimately dispersed and forms a separate phase in the hydrophilic polyurethane. When the coating becomes wet, the hydrophilic polyurethane swells and the polyvinyl pyrrolidone bleeds to the surface to form a lubricating film on the guide portion of the medical device.

U.S. Pat. No. 4,997,901, issued to Ofstead, also discloses medical devices coated with a hydrophilic polymer and lists polyvinyl alcohol which is more than about 88% hydrolyzed, as the preferred hydrophilic polymer.

U.S. Pat. No. 4,884,579, issue to Engelson, discloses a catheter guide wire and lists several polymers that can be used as cover materials to provide a low friction surface. Two of the cover materials listed are polyurethane and polyvinyl pyrrolidone.

U.S. Pat. No. 4,729,914, issued to Kliment et al., discloses the application of N-vinyl pyrrolidone copolymers to a substrate having free isocyanate groups. A chemical reaction then occurs between the N-vinyl pyrrolidone and the isocyanate groups of the substrate, causing the formation of a chemically linked polyvinyl pyrrolidone which has less tendency to leach.

U.S. Pat. No. 4,682,607, issued to Vaillancourt et al., discloses a wire guide provided with a polymer coating which can be a hydrophilic material such as polyvinyl pyrrolidone, polyurethane or hydroxyethyl methacrylate.

European Patent Application 0 405 823A2 discloses generally the use of a hydrophilic coating on the outside surface of a guide wire, to reduce friction.

One of the disadvantages of hydrophilic coatings known in the art is that they tend to leach and can become easily separated from the substrate. Separation can be prevented to some extent by providing for a chemical reaction between the coating and substrate to anchor the hydrophilic coating to the substrate. However, this creates the additional risk that quantities of undesirable, unreacted chemicals will be present in the coating. Thus, there is a need to improve adhesion between hydrophilic coatings and substrates without using a chemical reaction.

SUMMARY OF THE INVENTION

In accordance with the present invention, a medical insertion device is provided which has a distal guide portion that is either composed of or is jacketed with a hydrophobic polymer substrate material. The term "hydrophobic" refers to polymers which lack an affinity for water. Hydrophobic polymers do not dissolve in water when in the thermoplastic state and do not swell or swell only to a limited degree in the presence of water whether in the thermoplastic or crosslinked state. For purposes of the present invention, the term "hydrophobic polymer" includes any polymer which does not dissolve and does not swell more than ten per cent by weight in room temperature water.

The hydrophobic polymer substrate is covered with a hydrophilic coating which is composed of a blend of a hydrophilic polymer and a hydrophobic polymer which is the same as or similar to the substrate. The term "hydrophilic" refers to polymers which have an affinity for water. Hydrophilic polymers tend to dissolve partially or totally in water when in the thermoplastic state, and tend to swell substantially in the presence of water when in the crosslinked state. For purposes of the present invention, the term "hydrophilic polymer" refers to any polymer which is water soluble when not crosslinked, or which is swellable to more than 100% by weight in room temperature water when crosslinked.

By including a hydrophobic polymer in the coating which is the same or similar to the hydrophobic polymer of the substrate, excellent adhesion between the coating and the substrate can be obtained without requiring a chemical reaction to anchor the coating to the substrate. Thus, the risk of having unreacted chemicals present on the surface of the guide portion of the insertion device is overcome. Also, by blending hydrophilic and hydrophobic polymers together, the leaching of the hydrophilic polymer is reduced. The hydrophilic polymer is believed to become ensnared in the hydrophobic medium. Finally, by including a hydrophobic polymer in both the substrate and the coating, the swelling of the guide portion of the medical device inside a vein or organ is reduced.

With the foregoing in mind, it is a feature and advantage of the invention to provide an improved guide portion for a medical insertion device which has a slippery, hydrophilic coating that has excellent adhesion to the guide portion.

It is also a feature and advantage of the invention to provide an improved guide portion for a medical insertion device which does not possess quantities of unre-

acted chemicals on its outer surface or in the hydrophilic coating thereof.

It is also a feature and advantage of the invention to provide an improved guide portion for a medical insertion device having a slippery, hydrophilic surface which is less prone to leaching and separation of the hydrophilic polymer contained therein.

It is also a feature and advantage of the invention to provide an improved guide portion for a medical insertion device which has a reduced tendency to undergo swelling due to moisture absorption inside a vein or organ.

The foregoing and other features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, taken in conjunction with the accompanying figures. It is understood that the detailed description and figures are to be construed as illustrative rather than limitative, the scope of the invention being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE FIGURES

FIG. **1** is a sectional view of a first embodiment of the present invention.

FIG. *2a* shows a cross section of the embodiment of FIG. **1** along line *2a–2a*.

FIG. *2b* shows a cross section of the embodiment of FIG. **1** along line *2b–2b*.

FIG. *2c* shows a cross section of the embodiment of FIG. **1** along line *2c–2c*.

FIG. **3** is a sectional view of a second embodiment of the invention.

FIG. **4** is a sectional view of a third embodiment of the invention.

BRIEF DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

The present invention is directed toward an improved substrate and coating combination for the distal (i.e. leading) guide portion of any medical insertion device such as catheters, probes, guide wires, pacemakers and other devices, which are inserted for medical purposes into the human body. For purposes of exemplification only, the following detailed description is made with reference to the improved guide wire which is described in the parent U.S. application Ser. No. 07/716,678, filed on Jun. 18, 1991, the entire disclosure of which is incorporated by reference.

Referring to FIG. **1** there is depicted a first preferred embodiment of the present invention. This embodiment is an intravascular guide wire **10**. This guide wire **10** has a distal end **12** and a proximal end **14**. The guide wire **10** may be approximately 180 centimeters in length and have an outside diameter of approximately 0.035 inches. Other lengths and diameters may be provided so that a range of sizes of guide wires may be available for the different needs of various individual patients and the preferences of physicians. Such other sizes are contemplated within the scope of the present invention and of this embodiment in particular.

The guide wire **10** includes a core **18**. The core may be made of a strong, yet flexible material, such as a metal, like stainless steel or nitinol, or other materials, or combinations thereof. In a preferred embodiment, the core **18** is made at least in part of a selectively formable metallic material, as explained in more detail below. The core **18** extends from the distal end **12** to the proximal end **14** of the guide wire **10**.

In a preferred embodiment, the core **18** includes a distal portion **20** and a proximal portion **22**. The proximal and distal portions are preferably formed of a single metallic wire. The distal portion **20** has a smaller cross section than the proximal portion **22** to impart greater flexibility to the distal end of the guide wire. In a preferred embodiment, the distal portion **20** of the guide wire comprises a series of stages or regions of tapered portions and portions of uniform cross section, as explained in more detail below. The series of stages of tapered portions and portions of uniform cross section are intended to impart increasing levels of flexibility to the guide wire toward the distal end.

In this embodiment, the proximal portion **22** of the core **18** has a diameter of approximately 0.018 inches. FIG. *2a* shows a cross section of the guide wire in the proximal portion **22**. The proximal portion **22** of the core **18** extends from a proximal end of the guide wire **10** to a proximal end of the distal portion **20** of the core **18**. In this embodiment, the distal portion **20** of the core **18** is approximately 6.75 inches in length.

The distal portion **20** of the core includes a first region **24** immediately adjacent to and distal of the proximal portion **22**. The first region **24** of the distal portion **20** of the core is approximately 2.0 inches in length. In the first region **24**, the core **18** tapers from the diameter of the proximal portion **20** (e.g. 0.018 inches) to a diameter of approximately 0.0105 inches. In this first region **24**, the core has a circular cross section.

The distal portion **20** of the core next includes a second region **28** immediately adjacent to and distal of the first region **24**. This second region **28** of the distal portion **20** of the core is approximately 1.0 inches in length. FIG. *2b* shows a cross section of the guide wire in this region. The second region **28** is a region of approximately uniform cross section. In this second region **28**, the core also preferably has a circular cross section.

The distal portion **20** of the core next includes a third region **30** immediately adjacent to and distal of the second region **28**. This third region **30** of the distal portion **20** of the core is approximately 2.0 inches in length. In the third region **30**, the core **18** tapers from the diameter of the second region **28** (e.g. 0.0105 inches) to a diameter of approximately 0.00525 inches. In this third region **30**, the core also has a circular cross section.

The distal portion **20** of the core next includes a fourth region **32** immediately adjacent to and distal of the third region **30**. This fourth region **32** of the distal portion **20** of the core is approximately 1.75 inches in length. In the fourth region **32**, the core **18** is flattened toward a distal end **34** thereof to form a ribbon shape having dimensions of approximately 0.010 by 0.00225 inches. FIG. *2c* shows a cross section of the guide wire in this region. The ribbon shape of this region causes the guide wire to tend to flex in one plane thereby facilitating the use thereof. In the fourth region **32**, the length of the distal flattened portion is approximately 0.5 inches, the length of the portion of circular cross section is approximately 0.7 inches, and a transition zone between these portions has a length of approximately 0.7 inches.

The distal portion **20** of the core wire, including the various regions of tapered and uniform cross section, may be formed by methods known in the art, such as chemical washes, polished, grinding or compressing.

The guide wire **10** also includes a plastic jacket **38** extending from the proximal end **14** to the distal end **12**. In a first preferred embodiment, the plastic jacket **38** is formed of a proximal jacket portion **40** and a distal jacket portion **42**. The outside diameter of the plastic jacket **38** in this embodiment is approximately 0.035 inches although other diameters may be provided for guide wires of other dimensions.

The distal jacket portion **42** is approximately 20 inches in length and extends proximally from the distal end of the guide wire **10**. The distal end of the distal jacket portion **42** extends over and covers the distal end of the core wire **18**. The proximal jacket portion **40** extends from the proximal end of the guide wire **10** distally. In this embodiment, the proximal end of the distal jacket portion **42** substantially abuts the distal end of the proximal jacket portion **40**. At the location at which the proximal and distal jacket portions abut, the outside diameters of the jacket portions are substantially the same and form a smooth transition at that location so that the guide wire can be readily inserted into and moved within a catheter or vessel or that a catheter or other device can be readily advanced over the guide wire.

These two jacket portions are provided to yield features related to functions specifically associated with their respective locations. In this embodiment, the proximal jacket portion **40** is made of a polytetrafluoroethylene (Teflon ®) material and the distal jacket portion **42** is made of a hydrophobic polymer material such as nylon, polyvinyl chloride, silicone, a fluoroelastomer, hydrophobic polyurethane, polyester, acrylic, polycarbonate, polyimides, or combinations thereof. The preferred material for the distal jacket portion **42** is hydrophobic polyurethane. The proximal jacket portion **40** may also be made of another material or combination of materials such as a fluororesin, high density polyethylene, polyacetal, Hytrel, Pebox, Nylon or polypropylene, or any of the hydrophobic materials listed above.

The distal jacket portion may be loaded with a radiopaque material in the range of 40% to 70%. In one preferred embodiment, the distal jacket portion is loaded with a 60% radiopaque material.

In accordance with the invention, the distal jacket portion **42** has a hydrophilic coating **43** applied to it to make its surface highly lubricous when it comes into contact with a fluid such as blood. The hydrophilic coating is believed to improve the biocompatibility of the guide wire **10**. This is based in part on observations that hydrophilic surfaces are generally less thrombogenic. The hydrophilic coating provides a slippery yet medically safe surface so that the guide wire can easily be inserted into the human body without causing injury, infection, or excessive discomfort.

The hydrophilic coating **43** includes a blend of about 10–90 weight per cent of a hydrophobic polymer and about 90–10 weight per cent of a hydrophilic polymer. Preferably, the hydrophilic coating **43** contains about 20–70 weight per cent hydrophobic polymer and about 80–30 weight per cent hydrophilic polymer, most preferably about 30–55 weight per cent hydrophobic polymer and about 70–45 weight per cent hydrophilic polymer. The hydrophobic component provides the coating **43** with an affinity to the hydrophobic substrate **42**, while the hydrophilic component is a slippery, otherwise water soluble material. The hydrophilic component tends not to dissolve away because it is ensnared with the water insoluble hydrophobic component.

The hydrophobic polymers which are suitable for use in the hydrophilic coating **43** include any of the aforementioned hydrophobic polymers or combinations thereof which can be used to construct the distal jacket portion **42**. Preferably, the hydrophobic component of the hydrophilic coating **43** is the same or very similar to the polymer of the distal jacket portion **42**, in order to promote excellent adhesion between the hydrophilic coating **43** and the distal jacket portion **42**. Most preferably, the hydrophobic component of the coating **43** is hydrophobic polyurethane, and the distal jacket portion **42** is also of hydrophobic polyurethane. Examples of suitable hydrophobic polyurethanes include Dow Pellethane 2363 series or Thermedics Tecophane or Tecoflex series.

The hydrophilic polymers which are suitable for use in the hydrophilic coating **43** include polyvinyl pyrrolidone, poly (ethylene oxide), poly (acrylic acid), poly (methacrylic acid), polyacrylamide, poly (hydroxyethyl acrylate), poly (hydroxyethyl methacrylate), polyvinyl alcohol, poly (sodium styrene sulfonate), poly (2-acrylamido-2-methylpropane sulfonic acid), poly (sodium vinyl sulfonate), poly (vinyl pyridine), proteins, copolymers of the foregoing, or combinations thereof. The preferred hydrophilic polymer is polyvinyl pyrrolidone. Polyvinyl pyrrolidone is used in many medical and drug applications, is well tolerated by the body, and is easily dissolved in solvent.

The coating material for the hydrophilic coating **43** can be prepared by dissolving both the hydrophobic polymer and the hydrophilic polymer, in the desired ratios, in a solvent system. The selection of a suitable solvent system involves consideration at the hydrophobic and hydrophilic polymer components and of the substrate **42** material which is to be coated. The solvent system should be able to swell or dissolve, in part, the substrate, so that the coating **43** can be securely bonded to the substrate **42**.

In the preferred embodiment, one approach is to use an organic solvent for the hydrophobic polyurethane and add enough water or alcohol to dissolve the polyvinyl pyrrolidone. Preferred solvent systems are dimethyl acetamide with water, dimethyl formamide with water, and tetrahydrofuran with water. Other solvent systems (which may in fact become preferred if certain hydrophobic and hydrophilic polymers are used) include hydrocarbons, halogenated solvents, ketones, ethers, amides, and water, in any compatible combinations. Typically, the mixture of solvents and hydrophobic and hydrophilic polymers contains about 0.1 to about 25 weight per cent solids, more commonly about 1 to about 15 weight per cent solids and most commonly about 4 to about 10 weight per cent solids.

In order to form the coating **43**, the mixture of solvents with hydrophobic and hydrophilic polymers is applied to the distal jacket portion **42** in an amount sufficient to completely coat the distal jacket portion **42**. Then, the solvents are allowed to dry. The coating **43** preferably blends with the substrate so that there is no clear boundary between the coating and the substrate.

In a preferred embodiment, the hydrophilic coating is applied only to a distal portion of the guide wire, and in particular, only to the distal jacket portion **42**. This is facilitated because the preferred hydrophilic coating is formulated to adhere to the urethane material of the distal jacket portion but not adhere to many different materials including the preferred material of the proximal jacket.

As mentioned above, the proximal jacket portion is made of polytetrafluoroethylene which also provides a low friction surface though not as low friction as that of the distal jacket portion with the hydrophilic coating applied. It is advantageous for the proximal portion of the guide wire to have a low friction surface in order to traverse a catheter lumen or a vessel. However, because the proximal portion of the guide wire will likely be in a portion of the vasculature not as tortuous as the distal portion, it would not require a surface of as high lubricity as the distal portion and therefore polytetrafluoroethylene or any of the other previously mentioned proximal materials with or without a silicone coating, is a good choice of materials.

Moreover, this combination of low friction surfaces has the additional advantage that a very low friction surface, such as one having a hydrophilic coating, is used only on the distal portion of the guide wire. A very low friction surface, such as one having a hydrophilic coating, would be so slippery that it would be difficult for a physician to handle if it were on the proximal end as well. Accordingly, at the proximal end of the guide wire, this embodiment includes a surface that is easy for the physician who would be manipulating the guide wire from the proximal end to handle and yet is of sufficiently low friction so that it can readily traverse portions of the patient's vessels and provide good guide wire movement in a catheter.

It is also preferred that the distal portion of the guide wire be provided with enhanced radiopaque properties. In the preferred embodiment, this is done by loading the material from which the distal jacket **42** is made with radiopaque materials such as barium, bismuth or tungsten. The loading of the distal jacket of polyurethane with a radiopaque material enhances the ability of a physician to observe the position of the distal end of the guide wire in the body of the patient by means of fluoroscopy.

In a preferred embodiment, the proximal jacket portion **40** of polytetrafluoroethylene is heat shrunk onto the core wire. The distal jacket portion **42** is installed over the core wire by heating a sleeve of polyurethane to a temperature until it is reformed around the core wire. The proximal and distal jackets may be finished by a centerless grinding method so that the transition between the jacket portions is smooth.

In a further embodiment, the guide wire has a core that is selectively formable at least in a distal portion thereof. By a selectively formable core, it is meant that the wire from which the core is made may be bent to a particular shape and that the shape will be maintained by the wire. This allows the physician to impart a particular shape to the guide wire, by bending or kinking it for example, to facilitate its placement into a patient's vasculature. To provide this selective formability, in a preferred embodiment, the entire core wire may be made of stainless steel. Other materials may be used to provide this feature. The use of a formable material, such as stainless steel, provides advantages in the guide wire over materials that cannot be formed, such as superelastic materials like nitinol. Superelastic materials, like nitinol are so resilient that they tend to spring back to their original shape even if bent, thus are not formable. Although superelastic material may be provided with a "preformed" memory shape, such a preformed shape is typically determined in the manufacture of the guide wire and cannot readily be altered or modified by the physician by simply bending the guide wire prior to use. Although use of superelastic materials such as nitinol in guide wire applications may provide some advantages in certain uses, a formable core, such as of stainless steel, which can be formed by the physician to a shape suitable for a particular patient or preferred by that physician, provides an advantage that cannot be obtained with a superelastic core guide wire.

In a further preferred embodiment, the guide wire may include a core wire of a material having formable properties at a distal portion thereof and non-formable (e.g. superelastic properties) proximally. Such a construction would provide advantages in certain guide wire usages. A guide wire having these properties could be formed by using a superelastic material such as nitinol for the core wire and reducing its superelasticity in a distal portion thereof. This may be effected by heating the distal end of the superelastic core wire. Another means to reduce the superelastic properties of a distal end of the core wire would be to shape it mechanically, e.g. flattening it. Other methods of reducing the superelastic properties of the core wire may also be used. With a core wire having this dual combination of a formable distal portion and a superelastic proximal portion, desired shapes could be imparted by a physician to the distal end of the guide wire to facilitate making turns, etc., in tortuous vessel passages, while in the same guide wire the more proximal portion would possess superelastic properties to allow it to follow the distal portion through the tortuous passages without permanently deforming. This combination of formable and non-formable properties in the core wire may also be provided by using more than one material for the core wire or more than one wire.

FIG. **3** shows another preferred embodiment of the present invention. This embodiment of the guide wire is similar in some respects to the embodiment of the guide wire, described above. Although this embodiment of the guide wire may be provided in large sizes (e.g. 0.035 inches), this embodiment is especially suitable for a guide wire of a smaller diameter, e.g. having an outer diameter of approximately 0.018 inches. If provided in a guide wire of smaller diameter, the diameter of the core wire and plastic jacket would be correspondingly smaller. Like the embodiment described above, this guide wire includes a core **52** surrounded by a plastic jacket **54**. The core **52** is preferably of a selectively formable material, as described above. In addition, in this embodiment, a marker **56** is provided at a distal end **58** of the guide wire **50**. This marker **56** is located around the distal portion of the core wire **52** underneath the plastic jacket **54**. In this embodiment, the marker **56** is a coil spring. Alternatively, the marker may be a ribbon, another wire, or any other similar component. A tip **60** may be provided at the distal end of the core wire **52** to facilitate placement and connection of the marker **56**.

The marker **56** may be made of platinum or stainless steel or other material. The marker **56** may be provided with radiopaque properties by selecting a material such as platinum. This may be in addition or as an alternative to providing radiopaque properties in the jacket portion through the use of loading with radiopaque materials. The use of a radiopaque marker may be preferred in smaller diameter guide wires where the plastic jacket, even if loaded with a radiopaque material, is of such a small size that it could be difficult to discern under fluoroscopy.

FIG. 4 shows another preferred embodiment of the present invention. In the embodiment in FIG. 4, a core wire 20 extends from a distal to a proximal end of the guide wire. As in the embodiment described above, the core wire 20 is surrounded by a core wire jacket 38. In this embodiment, the core wire jacket 38 is comprised of a first jacket 70. The first jacket 70 of this embodiment is comprised of a first portion 72 and a second portion 74. The core wire jacket 38 also includes a second jacket 76. The second jacket 76 covers the first jacket 70 over the second portion 74 thereof. The second jacket 76 may correspond to the proximal jacket of the previous embodiments. The second jacket 76 may be a thin tubing that is heat shrunk onto the first jacket 70 over a proximal portion thereof. Alternatively, the second jacket 76 may be applied by other methods, such as by spraying, dipping, etc.

In a preferred embodiment, the outer diameter of the second jacket 76 when it is in position surrounding the first jacket 70 is approximately the same as the outer diameter of the first jacket 70 in the first portion 72 thereof at least in an area 80 of the guide wire where the second jacket 76 ends so that the overall diameter of the guide wire through this area 80 is substantially uniform. This uniformity may be further enhanced by polishing, grinding, or other means. To further provide for this uniformity in diameter, the second portion 74 of the first jacket 70 may be provided with a diameter that is less than that of the first portion 72 of the first jacket 70. This reduction in diameter may be formed by grinding, stretching, chemical erosion, or other means.

In a preferred embodiment, the second jacket 76 covers the proximal portion of the guide wire and an exposed first portion 72 of the first jacket 70 extends to a distal end of the guide wire. The first jacket 70 and second jacket 76 may be provided with properties specifically directed to their respective functions, as explained above in regard to the embodiment of the guide wire in which the jackets are in an abutting relationship. For example, the first jacket 70 may be made of polyurethane and the second jacket 76 may be made of a Teflon-like material. A hydrophilic coating may be applied to the first jacket 70 in the first portion 72 thereof to enhance lubricity, as explained above. If this embodiment of the guide wire is intended for use in peripheral regions of the body, it may have an outside diameter of approximately 0.035 inches. Other dimensions may be suitable as well for other size guide wires. As in the previously described embodiments, the core 20 may be a material such as stainless steel or nitinol and may have formable properties in at least a portion thereof.

It is intended that the foregoing detailed description be regarded as illustrated rather than limiting and that it is understood that the following claims including all equivalents are intended to define the scope of the invention.

We claim:

1. A guide for medical insertion device comprising:
a core;
a jacket surrounding the core, the jacket being composed of a hydrophobic polymer; and
a hydrophilic coating applied to the jacket, the hydrophilic coating being composed of a blend of about 10 to about 90 weight percent of a hydrophobic polymer and about 90 to about 10 weight percent of a hydrophilic polymer;
the hydrophilic coating being free of unreacted chemicals;
the guide being free of chemical reaction between the hydrophilic coating and the jacket;
the hydrophobic polymer of the jacket and the hydrophobic polymer of the hydrophilic coating comprising the same polymer, said hydrophobic polymer being selected from the group consisting of nylon, polyvinyl chloride, silicone, fluroelastomers, polyester, acrylic, polycarbonate, polyimides, and combinations thereof; and
the hydrophilic polymer of the coating being selected from the group consisting of polyacrylamide, polyvinyl alcohol, poly(sodium styrene sulfonate), poly(2-acrylamido-2-methylpropane sulfonic acid), poly(sodium vinyl sulfonate), poly(vinyl pyridine), proteins, and combinations thereof.

2. The guide of claim 1, wherein the hydrophilic coating comprises about 20 to about 70 weight per cent of the hydrophobic polymer and about 80 to about 30 weight per cent of the hydrophilic polymer.

3. The guide of claim 1, wherein the hydrophilic coating comprises about 30 to about 55 weight per cent hydrophobic polymer and about 70 to about 45 weight per cent hydrophilic polymer.

4. A guide for medical insertion device comprising:
a core;
a jacket surrounding the core, the jacket comprising a hydrophobic polymer selected from the group consisting of nylon, polyvinyl chloride, silicone, fluroelastomers, polyester, acrylic, polycarbonate, polyimides, and combinations thereof; and
a hydrophilic coating applied to the jacket, the hydrophilic coating comprising a blend of said hydrophobic polymer with a hydrophilic polymer selected from the group consisting of polyacrylamide, polyvinyl alcohol, poly(sodium styrene sulfonate), poly(2-acrylamido-2-methylpropane sulfonic acid), poly(sodium vinyl sulfonate), poly(-vinyl pyridine), proteins and combinations thereof;
the hydrophilic coating being free of unreacted chemicals; and
the guide being free of chemical reaction between the hydrophilic coating and the jacket.

5. The guide of claim 1, wherein the hydrophilic polymer comprises polyvinyl pyrrolidone.

6. A guide for medical insertion device comprising:
a core;
a jacket surrounding the core, the jacket being composed of a hydrophobic polymer; and
a hydrophilic coating applied to the jacket, the hydrophilic coating being composed of a blend of about 10 to about 90 weight percent of a hydrophobic polymer and about 90 to about 10 weight percent of polyvinyl pyrrolidone;
the hydrophilic coating being free of unreacted chemicals;
the guide being free of chemical reaction between the hydrophilic coating and the jacket; and
the hydrophobic polymer of the jacket and the hydrophobic polymer of the hydrophilic coating comprising the same polymer, said hydrophobic polymer being selected from the group consisting of nylon, silicone, fluroelastomers, polyester, polycarbonate, polyimides, and combinations thereof.

7. The guide of claim 6, wherein the hydrophilic coating comprises about 20 to about 70 weight per cent

of the hydrophobic polymer and about 80 to about 30 weight per cent of polyvinyl pyrrolidone.

8. The guide of claim 6, wherein the hydrophilic coating comprises about 30 to about 55 weight per cent hydrophobic polymer and about 70 to about 45 weight per cent of polyvinyl pyrrolidone.

9. A guide for medical insertion device comprising:

a core;

a jacket surrounding the core, the jacket comprising a hydrophobic polymer selected from the group consisting of nylon, silicone, fluroelastomers, polyester, polycarbonate, polyimides, and combinations thereof; and

a hydrophilic coating applied to the jacket, the hydrophilic coating comprising a blend of said hydrophobic polymer with polyvinyl pyrrolidone;

the hydrophilic coating being free of unreacted chemicals; and

the guide being free of chemical reaction between the hydrophilic coating and the jacket.

* * * * *

EXHIBIT 8

78 USPQ2d 1329

In re Kahn

U.S. Court of Appeals
Federal Circuit

No. 04-1616

Decided March 22, 2006

441 F3d 977

Headnotes

PATENTS

[1] Practice and procedure in Patent and Trademark Office — Board of Patent Appeals and Interferences — In general (▶110.1101)

Patentability/Validity — Obviousness — Combining references (▶115.0905)

Patentability/Validity — Obviousness — Evidence of (▶115.0906)

Problem to be examined in considering motivation to combine prior art references is not specific problem solved by invention at issue, but general problem that confronted inventor before invention was made; thus, "motivation-suggestion-teaching" test asks not merely what references disclose, but whether person of ordinary skill in art, possessed with understandings and knowledge reflected in prior art and motivated by general problem facing inventor, would have been led to make claimed combination, and from this it may be determined whether overall disclosures, teachings, and suggestions of prior art, and level of skill in art, support legal conclusion of obviousness.

[2] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Substantial evidence supports conclusion that person of ordinary skill in art would have been motivated to combine teachings of prior art patent, which claims acoustical imaging system for use by visually impaired individuals, with teachings of two primary references to achieve invention of application claiming "reading machine" for use by blind persons, since prior patent teaches that its invention relates to augmentation of vision of those who have lost vision or have had their visual faculties diminished, that it is useful in teaching such persons "to apprehend the position of a virtual sound source as representing a point in space," and that it may be used as "rudimentary reading device," and since skilled artisan, who knows of "learning machine" that is capable of reading word aloud by selecting word on screen at which user is looking and seeks to provide visually-impaired user better control over word localization, would have reason to solve that problem by adding two-dimensional sound, in view of prior patent's express teaching that two-dimensional sound can be used to "substitute" for lost sense of sight, to locate point in space, and to create "rudimentary reading device" for visually impaired persons.

[3] Patentability/Validity — Obviousness — Person of ordinary skill in art (▶115.0902)

Patentability/Validity — Obviousness — Combining references (▶115.0905)

Board of Patent Appeals and Interferences did not overstate knowledge of person of ordinary skill in art, or employ improper hindsight, in making prima facie case of obviousness, since motivation to combine prior art

references to achieve invention claimed in application was articulated and placed on record.

[4] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Applicant's contention that person of ordinary skill in art would not have been motivated to combine prior art references to achieve invention claimed in application is without merit, since, even if applying secondary reference to primary reference resulted in device that would be less effective for primary reference's intended purpose, teaching of that reference is not limited to specific invention disclosed therein, since applicant may have

envisioned something different from skilled artisan in considering secondary reference, but artisan need not be motivated to combine secondary reference for same reason contemplated by applicant, and since secondary reference does not teach away from combination with primary reference, as there is nothing in secondary reference that would discourage person of skill in art from using device taught in primary reference in claimed combination, or that would lead skilled artisan in direction divergent from path taken by applicant.

[5] Patentability/Validity — Obviousness — Long felt need (▶115.0909)

Appellate court will not take judicial notice of long-felt need for device claimed in patent application, which is intended to help blind persons read, since finding either way on question of long-felt but unresolved need can reasonably be questioned, and long-felt need thus is not type of undisputed fact susceptible of judicial notice, and since precedent requires that applicant submit actual evidence of long-felt need, as opposed to argument, in that mere passage of time without claimed invention is not evidence of nonobviousness.

Case History and Disposition

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application of Leonard R. Kahn for patent on "reading machine" for use by blind persons. Applicant appeals from decision upholding rejection of claims in application for obviousness under 35 U.S.C. §103. Affirmed.

Attorneys

Leonard R. Kahn, New York, N.Y., pro se.

John M. Whealan, solicitor; Linda Moncys Isacson and Raymond T. Chen, associate solicitors, and Mary L. Kelly, U.S. Patent and Trademark Office, Arlington, Va., for Director, U.S. Patent and Trademark Office.

Judge

Before Michel, chief judge, and Linn and Prost, circuit judges.

Opinion Text

Opinion By:

Linn, J.

Leonard R. Kahn ("Kahn") appeals from the final decision of the Board of Patent Appeals and Interferences ("Board") concluding that claims 1–20 in patent application number 08/773,282 ("the '282 application") are unpatentable as obvious under 35 U.S.C. §103. [1] Because the factual findings underlying the Board's conclusion are supported by substantial evidence, and because the Board did not commit legal error in concluding that the claims would have been obvious, we affirm.

[1] The Board also affirmed its own rejection of claims 21 and 22 as being non-enabled under 35 U.S.C. §112, ¶ 1; however, in his opening brief on appeal Kahn withdrew those claims, leaving only claims 1–20 before us.

BACKGROUND

I. A. The Invention

The '282 application, filed on December 24, 1996 as a continuation-in-part of a series of continuing applications dating back to 1989, involves a "reading machine" that may be used by the blind. Prior to the application, machines that employed memory and display components by which material could be "read" using hand-held optical pens and speech synthesizers were known in the art. While a user can control these devices by hand to repeat words and to read at various speeds, such control is cumbersome, which makes it difficult for a blind user to study complex publications. Kahn addressed this problem and claims invention in a device that is operated by eye control and sound localization such that it can read out loud the word "looked at" by the user.

Kahn treats claims 1–20 as a group with claim 1 being representative:

> 1. A reading machine suitable for use by totally blind individuals for reading the complete text, or a selected portion thereof, of a document stored in storage means, at the option of the user, comprising:
>
> **Page 1331**
>
> (a) means of storing at least a portion of the text of the document to be read,
>
> (b) means for retrieving a selected portion of said stored text made available for immediate "reading,"
>
> (c) means for producing an acoustical display of the selected portion of said stored text, in a page-like format,

(d) means for determining the location on the acoustical display towards which the user is "looking," and

(e) means for generating speech sounds verbalizing the word that is formatted to appear on the acoustical display at the location the user is "looking" towards.

A preferred embodiment of the '282 patent is illustrated below in Figure 1.

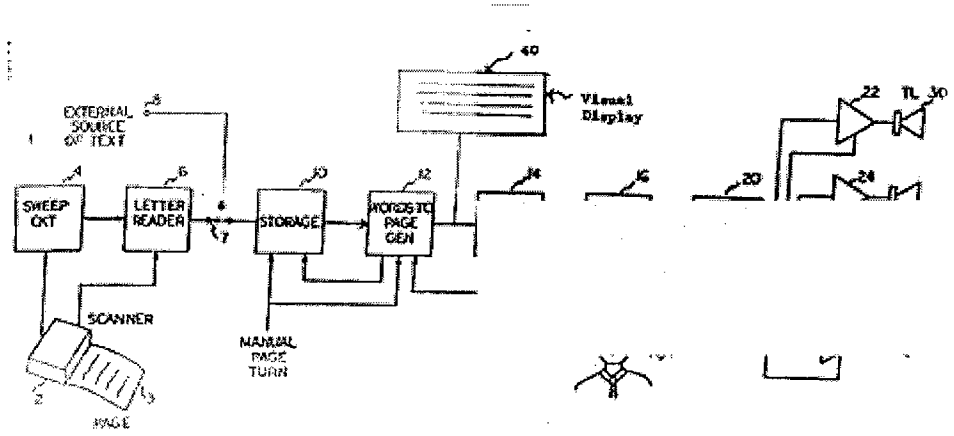


FIG.1

In operation,

> [t]he information being "read" ... is fed through intermediate storage means to speech synthesizer means for converting the written information to electrical waves representing speech sounds. These electric waves are fed to ... a four speaker array wherein the speakers are located in a fashion so that the artificial sound image can be placed at various points on the artificial screen or page allowing the user to hear the words at the desired locations. These locations would be selected by the user looking at a specific location on the artificial screen or page.
>
> The user would then move his or her eyes to "look" where the next word would be expected to appear, i.e., directly to the right of the spoken word. This would then cause the next word to be "spoken" and the sound image would appear slightly to the right. This motion is achieved by energizing the four speaker array with different levels of audio power....
>
> When the user completes the "reading" of the last word on the page, ... the reader would have the option of rereading a section on the page or causing the page to be "turned." If the user wishes to reread ..., he can direct his attention to the material to be reread by "looking" at the portion of the page where he remembers hearing the material.
>
> On the other hand, if he wishes to continue reading the material he can turn the page by looking along the bottom line past the right hand edge of the "page". The first word on the new page would be heard when the reader directed his or her attention to the upper left hand corner of the page where the first word on the new page would be expected.
>
> **Page 1332**

'282 application at 11-13.

According to the specification, the device can employ a conventional scanner to input data; a conventional character recognition device to translate and send data to a storage device; and a page generator to take data from the storage device and format it for a visual display and for a word selector, the latter of which can send the data to a conventional speech synthesizer. After an optical sensor detects where a user is "looking" and a word is "selected" for vocalization, the synthesizer feeds an audio signal to a localizer control. Loud speakers are arranged at the corners of the "page" to allow the user to confirm localization of sound. The specification further indicates that

> [t]here are a number of devices available for sensing where an individual is looking. For example, Garwin et. al. 4,595,990 ... , Anderson et. al. 4,579,533 ... and Stanton 4,322,744 ... . More specifically, Anderson's [sic] patent discusses feed-back which may be visual, auditory or tactile to verify decisions by eye control equipment.

> However, such inventions are not suitable for totally blind individuals who are not verifying where they are looking but are using their eyes to direct which part of the artificial page should be read to produce a sound image. This makes essential a two dimensional stereo sound stage which the blind person solely depends upon.

'282 application at 16.

B. The Prior Art

The Board's rejection was based on Garwin et al., U.S. Patent No. 4,595,990 (issued June 17, 1986) ("Garwin"), in view of Anderson et al., U.S. Patent No. 4,406,626 (issued Sept. 27, 1983) ("Anderson '626"), Anderson et al., U.S. Patent No. 4,579,533 (issued April 1, 1986) ("Anderson '533"), and Stanton, U.S. Patent No. 4,322,744 (issued March 30, 1982) ("Stanton"). The Board alternatively used Anderson '626 or '533 as primary references.

Garwin discloses an eye-controlled interactive information processor that senses the portion of a visual display at which the user is looking. The processor is connected to the display, which, in turn, can be partitioned so that different information is displayed in discrete areas. By gazing in different directions, the user informs the processor of the displayed item that is selected. Garwin, col. 2, ll. 60-68. The preferred embodiment employs a reflected light eye-tracking device to determine where the user is looking. *Id.*, col. 3, l. 66–col. 4, l. 62. The eye-interactive control generally uses a technique where the user is presented with a number of targets having some meaning, such as "words or phrases" displayed on screen. *Id.*, col. 9, ll. 62-67. "Visual, auditory or tactile" feedback is then given to the user to indicate that a selection has been received. *Id.*, col. 2, ll. 10-11; col. 11, ll. 59-64. The user then can verify or cancel the selection. *Id.*, col. 10, ll. 1-6. Garwin states that "it will be apparent to one skilled in the art that ... the benefits of the invention will be achieved by many types of apparatus." *Id.*, col. 2, ll. 50-53. It can be used for "request[ing] display of a page of text from a ... table of contents," *id.*, col. 3, ll. 42-44, or "[other] presentation of textual material," *id.*, col. 10, ll. 31-33.

Anderson '626 discloses an interactive "electronic teaching aid" which enables a user viewing text on a display to designate any words or portion of text for immediate audible vocalization. Anderson '626, col. 1, l. 8; col. 2, ll. 11-17. The components include: a selector switch, which when in the "text" position, causes data to be transmitted to a monitor and displayed in legible form, *id.*, col. 3, ll. 27-31; an advance button, which when depressed allows the user to select and retrieve the next page of text from memory, *id.*, col. 3, ll. 31-41; a memory, which can store each word of the text coded for speech, *id.*, col. 3, l. 66–col. 4, l. 6; and a word designator light pen, which the user can place on a word to hear the word vocalized through the speaker, *id.*, col. 3, ll. 54-68; col. 10, ll. 51-58. Anderson '533 discloses an improved microprocessor-based version of Anderson '626. Anderson '533, col. 1, ll. 19-24, 41-56.

Stanton discloses an acoustical imaging system for use by visually impaired individuals that uses horizontal and vertical directional sound to represent visual aspects of an environment. Stanton states that a user can locate "the position of a virtual sound source as representing a point in space" such that different signals may represent different directions. Stanton, col. 1, ll. 58-61. The preferred embodiment features four loud speakers or transducers mounted at the corners of a vertical display panel. *Id.*, col. 2, ll. 54-55. When the user moves the cursor, the sound emanating

Page 1333

from the speakers is phase shifted to produce a virtual sound seeming to come from a particular location related to the position of the cursor. *Id.*, col. 1, l. 66–col. 2, l. 2; col. 2, ll. 55-63. In another embodiment, a quadraphonic headset is used in place of the transducers to achieve the effect of producing a virtual sound identifying a position. *Id.*, col. 4, ll. 26-35. Stanton states that the device may be used as a "rudimentary reading device." *Id.*, col. 1, ll. 62.

C. The Board Decisions

Kahn filed the '282 application with 22 claims as a continuation-in-part of application number 07/645,102 ("the '102 application"), which was filed in 1991. The '102 application was a continuation-in-part of a series of abandoned continuing applications dating back to application number 07/338,597, which was filed in 1989. While claims 21 and 22 of the '282 application are not at issue in this appeal, the Board addressed those claims on several occasions, which led to the creation of a substantial Board history. As a result, the final decision with respect to the obviousness rejection of claims 1–20 spans three decisions, which include *Ex Parte Kahn*, No. 2004-1091 (B.P.A.I. June 30, 2004) ("*2004 decision*"); *Ex Parte Kahn*, No. 2000-1130 (B.P.A.I. Feb. 24, 2003) ("*2003 decision*"); and *Ex Parte Kahn*, No. 94-2233 (B.P.A.I. Sept. 21, 1995) ("*1995 decision*").

In its 1995 decision, after reversing the examiner's anticipation rejection, the Board *sua sponte* rejected the relevant claims under §103. The Board found that Garwin taught "the concepts of determining where on a display screen a user is 'looking' ... and giving either visual or *auditory* feedback to the user" and that "[w]hile nothing specific is said as to acoustically reproducing a word displayed at that location, common sense ... indicate[s] that such an auditory feedback response is appropriate in view of such *auditory* feedback confirmation clearly suggested by Anderson '533 or '626." *1995 decision*, slip op. at 5 (emphasis in original). The Board found that "to whatever extent Garwin is not concerned with text *per se*, [the Anderson] references are" and "teach the advantages of text display with audio reproduction," concluding that

> the artisan would have found it to have been obvious to have modified Garwin for display of text passages and selection of works therefrom with vocalization thereof as

> feedback confirmation, all as taught by Anderson '626 or '533 ... [or] to have modified either of these Anderson references to use the eye control of Garwin so that the user's hands would have been free for other tasks.

Id., slip op. at 5-6. The Board found that Stanton "teaches the benefit of acoustic imaging in reading systems" and that "[i]t would have, thus, been further obvious to the artisan to add advantageous acoustic imaging to either of the above-noted modified devices of Garwin or the Anderson patents which would have word positions acoustically and visually indicated." *Id.*, slip op. at 6.

In its *2003 decision*, the Board expressly incorporated the findings and rationale from both its *1995 decision* and the Examiner's Answer filed on April 24, 2000. *2003 decision*, slip op. at 3-4. In the Answer, the Examiner had explained that Garwin teaches "a buffer memory which stores at least a portion of the information derived from sensing means and means for subsequently retrieving the sensed information," "means for displaying stored written text," and "means for determining which word of the displayed text the user is looking towards"; that Anderson '626 teaches "means for generating speech sounds verbalizing the looked at word"; and that Stanton teaches "means for verbalizing each word the user's eyes are directed towards in two dimensional stereo." Examiner's Answer at 5-6. Rejecting Kahn's argument that hindsight drove the combination of references, the Board reiterated that the rationale of the 1995 decision was correct and explained that motivation "clearly is based upon a prospective look at the state of the art." *2003 decision*, slip op. at 8-11.

The Board addressed several other arguments. First, the Board rejected the argument that the invention's intended use supports patentability, noting that "the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus [from] a prior art apparatus satisfying the claimed structural limitations." *Id.* at 5-6. Second, the Board rejected the argument that because "the purposes of the [prior art] references ... are different from the [invention's] purpose," the invention is non-obvious, explaining that "[t]he law ... does not require that references be combined for reasons contemplated

Page 1334

by an inventor" and that "prior art need not suggest the same problem set forth by appellant." *Id.* at 6-7. Third, the Board rejected the arguments that features of a secondary reference be capable of incorporation into the structure of a primary reference and that the invention be suggested completely by one reference. *Id.* at 7. Finally, the Board rejected a "long-felt need" argument, explaining that Khan had not presented any objective evidence of a long-standing problem or long-standing need in the art. *Id.* at 11-12.

In its *2004 decision*, the Board entered a final rejection of claims 1–20 based on its *2003 decision*. Kahn timely appealed to this court. We have jurisdiction pursuant to 28 U.S.C. §1295(a)(4)(A).

II. DISCUSSION

A. The Parties' Arguments

Khan advances two main arguments. First, Khan asserts that the Board's finding of motivation to combine was unsupported by substantial evidence. Citing *In re Lee*, 277 F.3d 1338 [61 USPQ2d 1430] (Fed. Cir. 2002), and *In re Rouffet*, 149 F.3d 1350 [47 USPQ2d 1453] (Fed. Cir. 1998), Khan argues that the Board overstated the knowledge of the skilled artisan and employed improper hindsight. Specifically, Khan asserts that a skilled artisan would not have sought to augment Garwin with sound because the resulting device would be more expensive and less reliable for the purpose intended by Garwin. He contends that just because Stanton teaches use of sound to confirm a visual perception of a shape like a letter—which provides a "rudimentary" reading capability—does not mean that the reference teaches how to enable a blind user to "read" and "reread" entire words and phrases quickly. Khan further contends that Stanton teaches away from a system that employs iris eye direction sensing because Stanton requires the user to hold his head steady, because eyes are not involved in its localization procedure, and because the combined device would be expensive and inoperable. Second, Khan argues that the court should take "judicial notice" that his reading machine addresses a "long-felt, but unresolved need," and that this consideration is sufficient to rebut a *prima facie* case of obviousness.

The Patent and Trademark Office ("PTO") counters that *Lee* and *Rouffet* are distinguishable because here the Board identified motivations to combine the references based on specific statements in the references and on the nature of the problem to be solved. As to long-felt need, the PTO argues that Kahn proffered no actual evidence, and that Kahn's argument alone is insufficient to rebut a *prima facie* case.

B. Standard of Review

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art. 35 U.S.C. §103(a) (2000); *Graham v. John Deere Co.*, 383 U.S. 1, 13-14 [148 USPQ 459] (1966). The ultimate determination of whether an invention would have been obvious is a legal conclusion based on underlying findings of fact. In re *Dembiczak*, 175 F.3d 994, 998 [50 USPQ2d 1614] (Fed. Cir. 1999). We review the Board's ultimate determination of obviousness *de novo*. *Id.* However, we review the Board's underlying factual findings, including a finding of a motivation to combine, for substantial evidence. *In re Gartside*, 203 F.3d 1305, 1316 [53 USPQ2d 1769] (Fed. Cir. 2000).

Substantial evidence is something less than the weight of the evidence but more than a mere scintilla of evidence. *Id.* at 1312 (citing Consol. *Edison Co. v. NLRB*, 305 U.S. 197, 229-30 (1938)). It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. *Consol. Edison*, 305 U.S. at 229-30. In reviewing the record, we must take into account evidence that both justifies and detracts from the factual determinations. *Gartside*, 203 F.3d at 1312 (citing *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 487-88 (1951)). We note that the possibility of drawing two inconsistent conclusions from the evidence does not prevent the Board's findings from being supported by substantial evidence. *Id.* Indeed, if a reasonable mind might accept the evidence as adequate to support the factual conclusions drawn by the Board, then we must uphold the Board's determination. *Id.*

C. Analysis

In assessing whether subject matter would have been non-obvious under §103, the Board follows the guidance of the Supreme

Page 1335

Court in *Graham v. John Deere Co.* The Board determines "'the scope and content of the prior art,'" ascertains "'the differences between the prior art and the claims at issue,'" and resolves "'the level of ordinary skill in the pertinent art.'" *Dann v. Johnston*, 425 U.S. 219, 226 [189 USPQ 257] (1976) (quoting *Graham*, 383 U.S. at 17). Against this background, the Board determines whether the subject matter would have been obvious to a person of ordinary skill in the art at the time of the asserted invention. *Graham*, 383 U.S. at 17. In making this determination, the Board can assess evidence related to secondary indicia of non-obviousness like "commercial success, long felt but unresolved needs, failure of others, etc." *Id.*, 383 at 17-18; *accord Rouffett*, 149 F.3d at 1355. We have explained that

> [t]o reject claims in an application under section 103, an examiner must show an unrebutted *prima facie* case of obviousness ... . On appeal to the Board, an applicant can overcome a rejection by showing insufficient evidence of *prima facie* obviousness or by rebutting the *prima facie* case with evidence of secondary indicia of nonobviousness.

Rouffett, 149 F.3d at 1355.

Most inventions arise from a combination of old elements and each element may often be found in the prior art. *Id.* at 1357. However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole. *Id.* at 1355, 1357. Rather, to establish a *prima facie* case of obviousness based on a combination of elements disclosed in the prior art, the Board must articulate the basis on which it concludes that it would have been obvious to make the claimed invention. *Id.* In practice, this requires that the Board "explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious." *Id.* at 1357-59. This entails consideration of both the "scope and content of the prior art" and "level of ordinary skill in the pertinent art" aspects of the *Graham* test.

When the Board does not explain the motivation, or the suggestion or teaching, that would have led the skilled artisan at the time of the invention to the claimed combination as a whole, we infer that the Board used hindsight to conclude that the invention was obvious. *Id.* at 1358. The "motivation-suggestion-teaching" requirement protects against the entry of hindsight into the obviousness analysis, a problem which §103 was meant to confront. *See* 35 U.S.C. §103 (stating that obviousness must be assessed "at the time the invention was made"); *Dembiczak*, 175 F.3d at 998 ("[I]t is this phrase that guards against entry into the tempting but forbidden zone of hindsight." (internal quotations omitted)); Giles S. Rich, *Laying the Ghost of the Invention Requirement*, 1 APLA Q.J. 26-45 (1972), *reprinted in* 14 Fed. Cir. B.J. 163, 170 (2004) ("To protect the inventor from hindsight reasoning, *the time is specified to be the time when the invention was made.*") (emphasis in original). The Supreme Court recognized the hindsight problem in *Graham* and proposed that "legal inferences" resulting from "secondary considerations" might help to overcome it. 383 U.S. at 36 ("[Secondary considerations] may also serve to guard against slipping into use of hindsight, and to resist the temptation to read into the prior art the teachings of the invention in issue." (internal quotations omitted)). By requiring the Board to explain the motivation, suggestion, or teaching as part of its *prima facie* case, the law guards against hindsight in all cases—whether or not the applicant offers evidence on secondary considerations—which advances Congress's goal of creating a more practical, uniform, and definite test for patentability. *See Dann*, 424 U.S. at 225-26 ("[I]t was only in 1952 that Congress, in the interest of 'uniformity and definiteness,' articulated the requirement in a statute." (quoting S. Rep. No. 1979, at 6 (1952); H.R. Rep. No. 1923, at 7 (1952))); *Graham*, 383 U.S. at 17 ("The §103 [test], when followed realistically, will permit a more practical test of patentability.").

Although our predecessor court was the first to articulate the motivation-suggestion-teaching test, a related test—the "analogous art" test—has long been part of the primary *Graham* analysis articulated by the Supreme Court. *See Dann*, 425 U.S. at 227-29; *Graham*, 383 U.S. at 35. [2] The analogous-art test

Page 1336

requires that the Board show that a reference is either in the field of the applicant's endeavor or is reasonably pertinent to the problem with which the inventor was concerned in order to rely on that reference as a basis for rejection. *In re Oetiker*, 977 F.2d 1443, 1447 [24 USPQ2d 1443] (Fed. Cir. 1992). References are selected as being reasonably pertinent to the problem based on the judgment of a person having ordinary skill in the art. *Id.* ("[I]t is necessary to consider 'the reality of the circumstances,'—in other words, common sense—in deciding in which fields a

person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor." (quoting *In re Wood*, 599 F.2d 1032, 1036 [202 USPQ 171] (C.C.P.A. 1979))). We have explained that this test begins the inquiry into whether a skilled artisan would have been motivated to combine references by defining the prior art relevant for the obviousness determination, and that it is meant to defend against hindsight. *See id.*; *In re Clay*, 966 F.2d 656, 659-60 [23 USPQ2d 1058] (Fed. Cir. 1992). [3]

---

[2] In *Graham*, Cook Chemical challenged the court's reliance on a reference that it believed was not in a "pertinent prior art," arguing that while the invention involved a container having a "pump sprayer," the reference related to containers having "pouring spouts." 383 U.S. at 35. In reaching the conclusion that the claimed subject matter was obvious, the Court rejected Cook's argument, explaining that the problem to be solved was a mechanical closure problem and that a closure device in such a closely related art was a pertinent reference. *Id.* Similarly, in *Dann*, the invention involved the use of automatic data processing equipment to analyze transactions within a single bank account. 425 U.S. at 227-28. The Dirk reference that the Court relied upon in making its obviousness case involved a similar system used in a non-banking context. *Id.* at 228. Citing *Graham*, the Court explained that a person of ordinary skill in the art would be aware of this reference and the Court could rely upon it in making its obviousness case because "[w]hile the Dirk's invention is not designed specifically for application to the banking industry many of its characteristics and capabilities are similar to those of respondent's system." *Id.* at 229.

[3] In *In re Clay*, we reasoned that

> [i]f a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it.

966 F.2d at 659-60. In *In re Oetiker*, we held that "the combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness." 977 F.2d at 1447.

The motivation-suggestion-teaching test picks up where the analogous art test leaves off and informs the *Graham* analysis. To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references, the Board must provide some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct. The requirement of such an explanation is consistent with governing obviousness law, *see* §103(a); *Graham*, 383 U.S. at 35; *Dann*, 425 U.S. at 227-29, and helps ensure predictable patentability determinations.

A suggestion, teaching, or motivation to combine the relevant prior art teachings does not have to be found explicitly in the prior art, as

> the teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references... . The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.

In re Kotzab, 217 F.3d 1365, 1370 [55 USPQ2d 1313] (Fed. Cir. 2000) (internal citations omitted). However, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. See *Lee*, 277 F.3d at 1343-46; *Rouffett*, 149 F.3d at 1355-59. This requirement is as much rooted in the Administrative Procedure Act, which ensures due process and non-arbitrary decisionmaking, as it is in §103. *See id.* at 1344-45.

[1] In considering motivation in the obviousness analysis, the problem examined is not the specific problem solved by the invention but the general problem that confronted the inventor before the invention was made. *See, e.g., Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323 [76 USPQ2d 1662] (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1372 [56 USPQ2d 1065] (Fed. Cir.

Page 1337

2000) ("Although the suggestion to combine references may flow from the nature of the problem, '[d]efining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness.'" (internal citation omitted) (quoting *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 [45 USPQ2d 1977] (Fed. Cir. 1998))); *In re Beattie*, 974 F.2d 1309, 1312 [24 USPQ2d 1040] (Fed. Cir. 1992) ("[T]he law does not require that the references be combined for the reasons contemplated by the inventor."); *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1337 [75 USPQ2d 1051] (Fed. Cir. 2005) (characterizing the relevant inquiry as "[would] an artisan of ordinary skill in the art at the time of the invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention,[ ] have selected

the various elements from the prior art and combined them in the manner claimed"); *see also Graham*, 383 U.S. at 35 (characterizing the problem as involving mechanical closures rather than in terms more specific to the patent in the context of determining the pertinent prior art). Therefore, the "motivation-suggestion-teaching" test asks not merely what the references disclose, but whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims. *See Cross Med. Prods.*, 424 F.3d at 1321-24. From this it may be determined whether the overall disclosures, teachings, and suggestions of the prior art, and the level of skill in the art—*i.e.*, the understandings and knowledge of persons having ordinary skill in the art at the time of the invention—support the legal conclusion of obviousness. *See Princeton Biochemicals*, 411 F.3d at 1338 (pointing to evidence supplying detailed analysis of the prior art and the reasons one of ordinary skill would have possessed the knowledge and motivation to combine).

In this case, Khan does not dispute that each element of his claimed invention can be found in either Garwin, Anderson '533 and '626, or Stanton, or that each reference lies in the pertinent art. Nor does Khan take issue with the Board's finding that a person having ordinary skill in the art would have been motivated to modify Anderson '533 or '626 in view of Garwin, or vice versa. *See* Garwin, col. 2, ll. 50-53, col. 10, ll. 31-35 (stating that "it will be apparent to one skilled in the art that ... the benefits of the invention will be achieved by many types of apparatus" which may be "virtually [any device] susceptible of control by a computer, including ... [those geared] to presentation of textual material").

Rather, Khan's challenge to the sufficiency of the evidence supporting the Board's *prima facie* case is directed at the motivation to apply the teachings of Stanton to achieve the claimed invention. In the 1995 decision, the Board found that Stanton "teaches the benefit of acoustic imaging in reading systems." The Board carefully examined the Anderson/Garwin combination and recognized that a skilled artisan confronted with the problem faced by Kahn would have been led by the teaching of Stanton "to add advantageous acoustic imaging" to the Anderson/Garwin combination so that it would have "word positions acoustically and visually indicated."

[2] Stanton teaches that "[its] invention relates to augmentation of vision of those who have lost vision or have had their visual faculties diminished," col. 1, ll. 6-8, that it is "useful in teaching a deprivee to apprehend the position of a virtual sound source as representing a point in space," *id.*, ll. 58-59, and that it may be used as a "rudimentary reading device," *id.*, ll. 61-62. A skilled artisan, who knows of a "learning machine" that is capable of reading a word aloud by selecting the word on the screen at which the user is looking and seeks to provide a visually-impaired user better control over word localization, [4] would have reason to solve that problem by adding two-dimensional sound in view of Stanton's express teaching that two-dimensional sound can be used to "substitute" for the lost sense of sight, to locate a point in space, and to create a "rudimentary reading device" for the visually impaired. *See Cross Med. Prods.*, 424 F.3d at 1323 (holding that "[o]ne of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings"). Because

Page 1338

the Board need only establish motivation to combine by a preponderance of the evidence to make its *prima facie* case, *see In re Glaug*, 283 F.3d 1335, 1338 [62 USPQ2d 1151] (Fed. Cir. 2002), we conclude that substantial evidence supports the finding of a motivation to combine the teachings of Stanton to the Anderson/Garwin combination. Although a reasonable person might reach the opposite conclusion, there is far more than a "mere scintilla" of evidence present from which a reasonable mind could find a motivation to combine.

[4] Kahn does not argue that one of ordinary skill in the art at the time of the invention would be unaware of the nature of this problem, and there is nothing in the record to suggest this to be the case, unlike the facts in the decision of our predecessor court in *In re Sponnoble*, 405 F.2d 578 [160 USPQ 237] (C.C.P.A. 1969).

[3] We reject Khan's argument that the Board overstated the knowledge of the person having ordinary skill in the art or employed improper hindsight in making its *prima facie* case. In both *Lee* and *Rouffet*, the Board recognized that the knowledge of the skilled artisan could provide the motivation to combine but concluded that no such knowledge was articulated and placed on the record. *Lee*, 277 F.3d at 1343-45; *Rouffet*, 149 F.3d at 1357-59. In this case, motivation to combine was articulated and placed on the record. As to the Anderson/Garwin combination, the Board identified the desire to free up the hands of the Anderson user as the problem confronted and found that Garwin itself evidenced the broad applicability of its optical controls to the claimed invention. As to the addition of Stanton, the Board identified express teachings in Stanton of "the benefit of acoustic imaging in reading systems" and properly related those teachings to the Anderson/Garwin combination.

[4] We find Khan's remaining arguments unpersuasive. First, even if applying Stanton to Garwin resulted in a device that would be less effective for the purpose intended by Garwin, the teaching of the Garwin reference is not limited to the specific invention disclosed. *See In re Heck*, 699 F.2d 1331, 1333 [216 USPQ 1038] (Fed. Cir. 1983) (explaining that "[t]he use of patents as references is not limited to what the patentees describe as their own inventions" (internal quotations omitted)). As noted above, Garwin states that his invention is intended to be applied to "virtually [any device] susceptible of control by a computer, including ... [those geared] to presentation of textual material," Garwin, col. 2, ll. 50-53; col. 10, ll. 31-35. Second, although Khan may have envisioned something different than the skilled artisan when he looked at Stanton because Stanton teaches only a *rudimentary* reading device, the skilled artisan

need not be motivated to combine Stanton for the same reason contemplated by Khan. *See In re Beattie*, 974 F.2d 1309, 1312 [24 USPQ2d 1040] (Fed. Cir. 1992) ("As long as some motivation or suggestion to combine the references is provided by the prior art taken as a whole, the law does not require that the references be combined for the reasons contemplated by the inventor." (citing *In re Kronig*, 539 F.2d 1300, 1304 [190 USPQ 425] (C.C.P.A. 1976))). Third, Khan's argument that Stanton itself teaches away from the combination with Garwin lacks support in the reference. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 [31 USPQ2d 1130] (Fed. Cir. 1994). Nothing in Stanton can be said to discourage a person having ordinary skill in the art from using the visual-input control taught in Garwin in the claimed combination or to lead the skilled artisan in a direction divergent from the path taken by Kahn.

[5] Finally, we note that Kahn had an opportunity to rebut the Board's *prima facie* case by offering evidence of objective indicia of non-obviousness. Khan put on no evidence, but invites this court to take "judicial notice" of the long-felt but unresolved need for a device that will help the blind read. We must decline Khan's invitation for the following reasons. First, "long-felt but unresolved need" is not the kind of undisputed fact to which courts are accustomed to taking "judicial notice" because a finding either way can "reasonably be questioned." *See* Fed. R. Evid. 201(b) ("A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned."); *In re Fielder*, 471 F.2d 640, 642-43 [176 USPQ 300] (C.C.P.A. 1973) (declining to take judicial notice of prior art references that appellant submitted as objective evidence of non-obviousness because appellant did not offer references to the Board and they were not part of the record). Second, our

Page 1339

precedent requires that the applicant submit actual evidence of long-felt need, as opposed to argument. This is because "[a]bsent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness." *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 [73 USPQ2d 1225] (Fed. Cir. 2004); *accord In re Wright*, 569 F.2d 1124, 1127 [193 USPQ 332] (C.C.P.A. 1977).

III. CONCLUSION

Because the factual findings underlying the Board's analysis, including the findings on motivation to combine, are supported by substantial evidence, we conclude that the Board did not err in rejecting claims 1–20 as *prima facie* obvious. Because Khan did not rebut the Board's *prima facie* case, the Board's decision is

AFFIRMED.

- End of Case -

ISSN 1526-8535

EXHIBIT 9

82 USPQ2d 1385
KSR International Co. v. Teleflex Inc.
U.S. Supreme Court

No. 04-1350

Decided April 30, 2007

127 SCt 1727

167 LEd2d 705

550 US 398

Headnotes

PATENTS

[1] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Rigid application of "teaching, suggestion, or motivation" test, under which patent claim is proved obvious only if prior art, nature of problem addressed by inventor, or knowledge of person having ordinary skill in art reveals some motivation or suggestion to combine prior art teachings, is inconsistent with expansive and flexible "functional approach" to resolution of obviousness issue, under which scope and content of prior art are determined, differences between prior art and claims at issue are ascertained, level of ordinary skill in pertinent art is resolved, and secondary considerations such as commercial success, long felt but unsolved needs, and failure of others may be considered if doing so would prove instructive; rigid TSM approach is therefore rejected.

[2] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Patentability/Validity — Obviousness — Evidence of (▶115.0906)

Variations of particular work available in one field of endeavor may be prompted by design incentives and other market forces, either in same field or different one, and if person of ordinary skill in art can implement predictable variation, 35 U.S.C. §103 likely bars its patentability; similarly, if particular technique has been used to improve one device, and person of ordinary skill would recognize that it would improve similar devices in same way, then using that technique is obvious unless its actual application is beyond person's skill, and court resolving obviousness issue therefore must ask whether improvement is more than predictable use of prior art elements according to their established functions.

[3] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Patentability/Validity — Obviousness — Evidence of (▶115.0906)

Court determining whether claimed combination of elements known in prior art would have been obvious will often be required to look to interrelated teachings of multiple patents, effects of demands known to design community or present in marketplace, and background knowledge of person of ordinary skill in art in order to determine whether there was apparent reason to combine known elements in manner claimed in patent in suit, and in order to facilitate review, this analysis should be made explicit; however, such analysis need not seek out precise teachings directed to specific subject matter of challenged claim, since court can take account of inferences and creative steps that person of ordinary skill in art would employ.

[4] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Idea underlying "teaching, suggestion, or motivation" test, under which patent claim is proved obvious only if prior art, nature of problem addressed by inventor, or knowledge of person having ordinary skill in art reveals some motivation or suggestion to combine prior art teachings, is not necessarily inconsistent with expansive and flexible "functional approach" to resolution of obviousness issue, since TSM test is based on helpful insights, namely, that patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in prior art, and that it can be important to identify reason that would have prompted person of ordinary skill in art to combine elements in manner claimed by new invention; however, it is

error to apply TSM test as rigid and mandatory formula that limits obviousness analysis through formalistic conception of words "teaching," "suggestion," and "motivation," or by overemphasis on importance of published articles and explicit content of issued patents, since market demand, rather than scientific literature, often drives design trends, and granting patent protection to advances that would occur "in the ordinary course" without real innovation retards progress and may, in case of patents

Page 1386

combining previously known elements, deprive prior inventions of their value or utility.

[5] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Narrow conception of obviousness inquiry, reflected in appellate court's application of "teaching, suggestion, or motivation" test, resulted in erroneous conclusion that summary judgment of obviousness should be vacated, since decision was based on erroneous holding that courts and patent examiners should look only to problem that patentee was trying to solve, and on erroneous assumption that person of ordinary skill in art attempting to solve problem will be led only to those elements of prior art designed to solve same problem, since court erroneously concluded that patent claim cannot be proved obvious merely by showing that combination of elements was "obvious to try," and since appellate court drew wrong conclusion from risk of courts and patent examiners falling prey to "hindsight" bias, in that rigid application of preventative rules that deny fact finders recourse to common sense are neither necessary nor consistent with precedent.

[6] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Patentability/Validity — Obviousness — Evidence of (▶115.0906)

Fact that claimed combination of elements was "obvious to try" might show that such combination was obvious under 35 U.S.C. §103, since, if there is design need or market pressure to solve problem, and there are finite number of identified, predictable solutions, person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation.

[7] Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (▶115.0903.03)

Patentability/Validity — Obviousness — Combining references (▶115.0905)

Asserted claim of patent for position-adjustable vehicle pedal assembly having electronic pedal-position sensor attached to fixed pivot point is invalid as obvious over combination of prior art references, since prior art patent discloses support structure for adjustable pedal assembly in which one pivot point stays fixed, since, at relevant time, marketplace had created strong incentive to convert mechanical pedals to those employing electronic sensors, and pedal designer of ordinary skill would have seen benefit in upgrading device of prior patent with sensor required by new engines using computer-controlled throttles, since other prior art references taught utility of placing sensor on pedal's support structure rather than on footpad, and on nonmoving part of pedal structure, since most obvious nonmoving point on structure from which sensor can easily detect pedal position is fixed pivot point, and since designer seeking to avoid wire-chafing problems with electronic adjustable pedals would have known to employ adjustable pedal with fixed pivot disclosed by prior art patent; declaration submitted by patentees does not indicate that device of prior patent was so flawed that there was no reason to upgrade it to be compatible with modern engines, and patentees have shown no secondary considerations to dislodge obviousness determination.

[8] Patentability/Validity — Obviousness — Evidence of (▶115.0906)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Summary judgment — Patents (▶410.3303)

Procedure — Evidence — Expert testimony (▶410.3703)

Party's submission of conclusory expert affidavit addressing issue of obviousness in patent action does not preclude summary judgment, even though federal district court can and should take into account expert testimony, which may resolve or keep open certain questions of fact, since ultimate judgment of obviousness is legal determination; in present case, in which content of prior art, scope of asserted claim, and level of ordinary skill in art were not in material dispute, and obviousness of claim was apparent from these factors, summary judgment was appropriate, and nothing in declarations proffered by patentees prevented district court from reaching conclusions underlying its order for summary judgment of obviousness.

Page 1387

Particular Patents

Particular patents — General and mechanical — Vehicle control pedal assembly

6,237,565, Engelgau, adjustable pedal assembly with electronic throttle control, invalid for obviousness.

Case History and Disposition

On writ of certiorari to the U.S. Court of Appeals for the Federal Circuit, Schall, J.

Action by Teleflex Inc. and Technology Holding Co. against KSR International Co. for patent infringement. The U.S. District Court for the Eastern District of Michigan granted summary judgment in favor of defendant on ground that patent in suit was invalid for obviousness, and plaintiffs appealed. Grant of summary judgment was vacated and remanded, and defendant-appellee filed petition for writ of certiorari. Reversed and remanded.

Attorneys

James W. Dabney, New York, N.Y.; Stephen S. Rabinowitz, Henry C. Lebowitz, Mitchell E. Epner, and Darcy M. Goddard, of Fried, Frank, Harris, Shriver & Jacobson, New York; John F. Duffy, of Fried, Frank, Harris, Shriver & Jacobson, Washington, D.C., for petitioner.

Thomas C. Goldstein, Michael A. O'Shea, Garreth A. Sarosi, Christopher R. Pudelski, and Sarah C. Rispin, of Akin Gump Strauss Hauer & Feld, Washington; Kenneth C. Bass III and Robert G. Sterne, of Sterne, Kessler, Goldstein & Fox, Washington; Rodger D. Young, Steven Susser, and David Poirier, of Young & Susser, Southfield, Mich.; Samuel J. Haidle and David M. LaPrairie, of Howard & Howard, Bloomfield Hills, Mich.; Tracy L. Casadio and Elizabeth H. Rader, of Akin Gump Strauss Hauer & Feld, Los Angeles, Calif., for respondent.

Syllabus

Syllabus by the Court.

To control a conventional automobile's speed, the driver depresses or releases the gas pedal, which interacts with the throttle via a cable or other mechanical link. Because the pedal's position in the footwell normally cannot be adjusted, a driver wishing to be closer or farther from it must either reposition himself in the seat or move the seat, both of which can be imperfect solutions for smaller drivers in cars with deep footwells. This prompted inventors to design and patent pedals that could be adjusted to change their locations. The Asano patent reveals a support structure whereby, when the pedal location is adjusted, one of the pedal's pivot points stays fixed. Asano is also designed so that the force necessary to depress the pedal is the same regardless of location adjustments. The Redding patent reveals a different, sliding mechanism where both the pedal and the pivot point are adjusted.

In newer cars, computer-controlled throttles do not operate through force transferred from the pedal by a mechanical link, but open and close valves in response to electronic signals. For the computer to know what is happening with the pedal, an electronic sensor must translate the mechanical operation into digital data. Inventors had obtained a number of patents for such sensors. The so-called '936 patent taught that it was preferable to detect the pedal's position in the pedal mechanism, not in the engine, so the patent disclosed a pedal with an electronic sensor on a pivot point in the pedal assembly. The Smith patent taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad. Inventors had also patented self-contained modular sensors, which can be taken off the shelf and attached to any mechanical pedal to allow it to function with a computer-controlled throttle. The '068 patent disclosed one such sensor. Chevrolet also manufactured trucks using modular sensors attached to the pedal support bracket, adjacent to the pedal and engaged with the pivot shaft about which the pedal rotates. Other patents disclose electronic sensors attached to adjustable pedal assemblies. For example, the Rixon patent locates the sensor in the pedal footpad, but is known for wire chafing.

After petitioner KSR developed an adjustable pedal system for cars with cable-actuated throttles and obtained its '976 patent for the design, General Motors Corporation (GMC) chose KSR to supply adjustable pedal systems for trucks using computer-controlled throttles. To make the '976 pedal compatible with the trucks, KSR added a modular sensor to its design. Respondents (Teleflex) hold the exclusive license for the Engelgau patent, claim 4 of which discloses a position-adjustable pedal assembly with an electronic pedal position sensor attached at a fixed pivot point. Despite having denied a similar, broader claim, the

Page 1388

U.S. Patent and Trademark Office (PTO) had allowed claim 4 because it included the limitation of a fixed pivot position, which distinguished the design from Redding's. Asano was neither included among the Engelgau patent's prior art references nor mentioned in the patent's prosecution, and the PTO did not have before it an adjustable pedal with a fixed pivot point. After learning of KSR's design for GMC, Teleflex sued for infringement, asserting that KSR's pedal system infringed the Engelgau patent's claim 4. KSR countered that claim 4 was invalid under §103 of the Patent Act, which forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art."

Graham v. *John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 [148 USPQ 459], set out an objective analysis for

applying §103: "[T]he scope and content of the prior art are ... determined; differences between the prior art and the claims at issue are ... ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." While the sequence of these questions might be reordered in any particular case, the factors define the controlling inquiry. However, seeking to resolve the obviousness question with more uniformity and consistency, the Federal Circuit has employed a "teaching, suggestion, or motivation" (TSM) test, under which a patent claim is only proved obvious if the prior art, the problem's nature, or the knowledge of a person having ordinary skill in the art reveals some motivation or suggestion to combine the prior art teachings.

The District Court granted KSR summary judgment. After reviewing pedal design history, the Engelgau patent's scope, and the relevant prior art, the court considered claim 4's validity, applying *Graham*'s framework to determine whether under summary-judgment standards KSR had demonstrated that claim 4 was obvious. The court found "little difference" between the prior art's teachings and claim 4: Asano taught everything contained in the claim except using a sensor to detect the pedal's position and transmit it to a computer controlling the throttle. That additional aspect was revealed in, *e.g.,* the '068 patent and Chevrolet's sensors. The court then held that KSR satisfied the TSM test, reasoning (1) the state of the industry would lead inevitably to combinations of electronic sensors and adjustable pedals, (2) Rixon provided the basis for these developments, and (3) Smith taught a solution to Rixon's chafing problems by positioning the sensor on the pedal's fixed structure, which could lead to the combination of a pedal like Asano with a pedal position sensor.

Reversing, the Federal Circuit ruled the District Court had not applied the TSM test strictly enough, having failed to make findings as to the specific understanding or principle within a skilled artisan's knowledge that would have motivated one with no knowledge of the invention to attach an electronic control to the Asano assembly's support bracket. The Court of Appeals held that the District Court's recourse to the nature of the problem to be solved was insufficient because, unless the prior art references addressed the precise problem that the patentee was trying to solve, the problem would not motivate an inventor to look at those references. The appeals court found that the Asano pedal was designed to ensure that the force required to depress the pedal is the same no matter how the pedal is adjusted, whereas Engelgau sought to provide a simpler, smaller, cheaper adjustable electronic pedal. The Rixon pedal, said the court, suffered from chafing but was not designed to solve that problem and taught nothing helpful to Engelgau's purpose. Smith, in turn, did not relate to adjustable pedals and did not necessarily go to the issue of motivation to attach the electronic control on the pedal assembly's support bracket. So interpreted, the court held, the patents would not have led a person of ordinary skill to put a sensor on an Asano-like pedal. That it might have been obvious to try that combination was likewise irrelevant. Finally, the court held that genuine issues of material fact precluded summary judgment.

Held: The Federal Circuit addressed the obviousness question in a narrow, rigid manner that is inconsistent with §103 and this Court's precedents. KSR provided convincing evidence that mounting an available sensor on a

Page 1389

fixed pivot point of the Asano pedal was a design step well within the grasp of a person of ordinary skill in the relevant art and that the benefit of doing so would be obvious. Its arguments, and the record, demonstrate that the Engelgau patent's claim 4 is obvious. Pp. 11–24.

1. *Graham* provided an expansive and flexible approach to the obviousness question that is inconsistent with the way the Federal Circuit applied its TSM test here. Neither §103's enactment nor *Graham*'s analysis disturbed the Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art. See *Great Atlantic & Pacific Tea Co.* v. *Supermarket Equipment Corp.*, 340 U.S. 147, 152 [87 USPQ 303]. Such a combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See, *e.g., United States* v. *Adams*, 383 U.S. 39, 50–52 [148 USPQ 479]. When a work is available in one field, design incentives and other market forces can prompt variations of it, either in the same field or in another. If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, §103 likely bars its patentability. Moreover, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions. Following these principles may be difficult if the claimed subject matter involves more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ. Pp. 11–14.

(b) The TSM test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. Although common sense directs caution

as to a patent application claiming as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does. Inventions usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known. Helpful insights, however, need not become rigid and mandatory formulas. If it is so applied, the TSM test is incompatible with this Court's precedents. The diversity of inventive pursuits and of modern technology counsels against confining the obviousness analysis by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasizing the importance of published articles and the explicit content of issued patents. In many fields there may be little discussion of obvious techniques or combinations, and market demand, rather than scientific literature, may often drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, for patents combining previously known elements, deprive prior inventions of their value or utility. Since the TSM test was devised, the Federal Circuit doubtless has applied it in accord with these principles in many cases. There is no necessary inconsistency between the test and the *Graham* analysis. But a court errs where, as here, it transforms general principle into a rigid rule limiting the obviousness inquiry. Pp. 14–15.

(c) The flaws in the Federal Circuit's analysis relate mostly to its narrow conception of the obviousness inquiry consequent in its application of the TSM test. The Circuit first erred in holding that courts and patent examiners should look only to the problem the patentee was trying to solve. Under the correct analysis, any need or problem known in the field and addressed by the patent can provide a reason for combining the elements in the

Page 1390

manner claimed. Second, the appeals court erred in assuming that a person of ordinary skill in the art attempting to solve a problem will be led only to those prior art elements designed to solve the same problem. The court wrongly concluded that because Asano's primary purpose was solving the constant ratio problem, an inventor considering how to put a sensor on an adjustable pedal would have no reason to consider putting it on the Asano pedal. It is common sense that familiar items may have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle. Regardless of Asano's primary purpose, it provided an obvious example of an adjustable pedal with a fixed pivot point, and the prior art was replete with patents indicating that such a point was an ideal mount for a sensor. Third, the court erred in concluding that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try. When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. Finally, the court drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. Rigid preventative rules that deny recourse to common sense are neither necessary under, nor consistent with, this Court's case law. Pp. 15–18.

2. Application of the foregoing standards demonstrates that claim 4 is obvious. Pp. 18–23.

(a) The Court rejects Teleflex's argument that the Asano pivot mechanism's design prevents its combination with a sensor in the manner claim 4 describes. This argument was not raised before the District Court, and it is unclear whether it was raised before the Federal Circuit. Given the significance of the District Court's finding that combining Asano with a pivot-mounted pedal position sensor fell within claim 4's scope, it is apparent that Teleflex would have made clearer challenges if it intended to preserve this claim. Its failure to clearly raise the argument, and the appeals court's silence on the issue, lead this Court to accept the District Court's conclusion. Pp. 18–20.

(b) The District Court correctly concluded that when Engelgau designed the claim 4 subject matter, it was obvious to a person of ordinary skill in the art to combine Asano with a pivot-mounted pedal position sensor. There then was a marketplace creating a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for doing so. The Federal Circuit considered the issue too narrowly by, in effect, asking whether a pedal designer writing on a blank slate would have chosen both Asano and a modular sensor similar to the ones used in the Chevrolet trucks and disclosed in the '068 patent. The proper question was whether a pedal designer of ordinary skill in the art, facing the wide range of needs created by developments in the field, would have seen an obvious benefit to upgrading Asano with a sensor. For such a designer starting with Asano, the question was where to attach the sensor. The '936 patent taught the utility of putting the sensor on the pedal device. Smith, in turn, explained not to put the sensor on the pedal footpad, but instead on the structure. And from Rixon's known wire-chafing problems, and Smith's teaching that the pedal assemblies must not precipitate any motion in the connecting wires, the designer would know to place the sensor on a nonmoving part of the pedal structure. The most obvious such point is a pivot point. The designer, accordingly, would follow Smith in mounting the sensor there. Just as it was possible to begin with the objective to upgrade Asano to work with a computer-controlled throttle, so too was it possible to take an adjustable electronic pedal like Rixon and seek an improvement that would avoid the wire-chafing problem. Teleflex has not shown anything in the prior art that taught away from the use of Asano, nor any secondary factors to dislodge the determination that claim 4 is obvious. Pp. 20–23.

3. The Court disagrees with the Federal Circuit's holding that genuine issues of material fact precluded summary judgment. The ultimate judgment of obviousness is a legal determination. *Graham*, 383 U.S., at 17. Where, as here, the prior art's content, the patent claim's scope, and the level of ordinary skill in the art are not in material dispute and the claim's obviousness

is apparent, summary judgment is appropriate. P. 23.

119 Fed. Appx. 282, reversed and remanded.

Kennedy, J., delivered the opinion for a unanimous Court.

Opinion Text

Opinion By:

Kennedy, J.

Teleflex Incorporated and its subsidiary Technology Holding Company—both referred to here as Teleflex—sued KSR International Company for patent infringement. The patent at issue, United States Patent No. 6,237,565 B1, is entitled "Adjustable Pedal Assembly With Electronic Throttle Control." Supplemental App. 1. The patentee is Steven J. Engelgau, and the patent is referred to as "the Engelgau patent." Teleflex holds the exclusive license to the patent.

Claim 4 of the Engelgau patent describes a mechanism for combining an electronic sensor with an adjustable automobile pedal so the pedal's position can be transmitted to a computer that controls the throttle in the vehicle's engine. When Teleflex accused KSR of infringing the Engelgau patent by adding an electronic sensor to one of KSR's previously designed pedals, KSR countered that claim 4 was invalid under the Patent Act, 35 U.S.C. §103, because its subject matter was obvious.

Section 103 forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

In *Graham* v. *John Deere Co. of Kansas City*, 383 U.S. 1 [148 USPQ 459] (1966), the Court set out a framework for applying the statutory language of §103, language itself based on the logic of the earlier decision in *Hotchkiss* v. *Greenwood*, 11 How. 248 (1851), and its progeny. See 383 U.S., at 15–17. The analysis is objective:

> "Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Id.*, at 17–18.

While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls. If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under §103.

Seeking to resolve the question of obviousness with more uniformity and consistency, the Court of Appeals for the Federal Circuit has employed an approach referred to by the parties as the "teaching, suggestion, or motivation" test (TSM test), under which a patent claim is only proved obvious if "some motivation or suggestion to combine the prior art teachings" can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art. See, *e.g.*, *Al-Site Corp.* v. *VSI Int'l, Inc.*, 174 F.3d 1308, 1323–1324 [50 USPQ2d 1161] (CA Fed. 1999). KSR challenges that test, or at least its application in this case. See 119 Fed. Appx. 282, 286–290 (CA Fed. 2005). Because the Court of Appeals addressed the question of obviousness in a manner contrary to §103 and our precedents, we granted certiorari, 547 U.S. ___ (2006). We now reverse.

I

A

In car engines without computer-controlled throttles, the accelerator pedal interacts with the throttle via cable or other mechanical link. The pedal arm acts as a lever rotating around a pivot point. In a cable-actuated throttle control the rotation caused by pushing down the pedal pulls a cable, which in turn pulls open valves in the carburetor or fuel injection unit. The wider the valves open, the more fuel and air are released, causing combustion to increase and the car to accelerate. When the driver takes his foot off the pedal, the opposite occurs as the cable is released and the valves slide closed.

In the 1990's it became more common to install computers in cars to control engine operation. Computer-controlled throttles open and close valves in response to electronic signals, not through force transferred from the pedal by a mechanical link. Constant, delicate

adjustments of air and fuel mixture are possible. The computer's rapid processing of factors beyond the pedal's position improves fuel efficiency and engine performance.

For a computer-controlled throttle to respond to a driver's operation of the car, the computer must know what is happening with the pedal. A cable or mechanical link does not suffice for this purpose; at some point, an electronic sensor is necessary to translate the mechanical operation into digital data the computer can understand.

Before discussing sensors further we turn to the mechanical design of the pedal itself. In the traditional design a pedal can be pushed down or released but cannot have its position in the footwell adjusted by sliding the pedal forward or back. As a result, a driver who wishes to be closer or farther from the pedal must either reposition himself in the driver's seat or move the seat in some way. In cars with deep footwells these are imperfect solutions for drivers of smaller stature. To solve the problem, inventors, beginning in the 1970's, designed pedals that could be adjusted to change their location in the footwell. Important for this case are two adjustable pedals disclosed in U.S. Patent Nos. 5,010,782 (filed July 28, 1989) (Asano) and 5,460,061 (filed Sept. 17, 1993) (Redding). The Asano patent reveals a support structure that houses the pedal so that even when the pedal location is adjusted relative to the driver, one of the pedal's pivot points stays fixed. The pedal is also designed so that the force necessary to push the pedal down is the same regardless of adjustments to its location. The Redding patent reveals a different, sliding mechanism where both the pedal and the pivot point are adjusted.

We return to sensors. Well before Engelgau applied for his challenged patent, some inventors had obtained patents involving electronic pedal sensors for computer-controlled throttles. These inventions, such as the device disclosed in U.S. Patent No. 5,241,936 (filed Sept. 9, 1991) ('936), taught that it was preferable to detect the pedal's position in the pedal assembly, not in the engine. The '936 patent disclosed a pedal with an electronic sensor on a pivot point in the pedal assembly. U.S. Patent No. 5,063,811 (filed July 9, 1990) (Smith) taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, and to avoid grime and damage from the driver's foot, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad.

In addition to patents for pedals with integrated sensors inventors obtained patents for self-contained modular sensors. A modular sensor is designed independently of a given pedal so that it can be taken off the shelf and attached to mechanical pedals of various sorts, enabling the pedals to be used in automobiles with computer-controlled throttles. One such sensor was disclosed in U.S. Patent No. 5,385,068 (filed Dec. 18, 1992) ('068). In 1994, Chevrolet manufactured a line of trucks using modular sensors "attached to the pedal support bracket, adjacent to the pedal and engaged with the pivot shaft about which the pedal rotates in operation." 298 F.Supp.2d 581, 589 (ED Mich. 2003).

The prior art contained patents involving the placement of sensors on adjustable pedals as well. For example, U.S. Patent No. 5,819,593 (filed Aug. 17, 1995) (Rixon) discloses an adjustable pedal assembly with an electronic sensor for detecting the pedal's position. In the Rixon pedal the sensor is located in the pedal footpad. The Rixon pedal was known to suffer from wire chafing when the pedal was depressed and released.

This short account of pedal and sensor technology leads to the instant case.

B

KSR, a Canadian company, manufactures and supplies auto parts, including pedal systems. Ford Motor Company hired KSR in 1998 to supply an adjustable pedal system for various lines of automobiles with cable-actuated throttle controls. KSR developed an adjustable mechanical pedal for Ford and obtained U.S. Patent No. 6,151,976 (filed July 16, 1999) ('976) for the design. In 2000, KSR was chosen by General Motors Corporation (GMC or GM) to supply adjustable pedal systems for Chevrolet and GMC light trucks that used engines with computer-controlled throttles. To make the '976 pedal compatible with the trucks, KSR merely took that design and added a modular sensor.

Teleflex is a rival to KSR in the design and manufacture of adjustable pedals. As noted, it is the exclusive licensee of the Engelgau patent. Engelgau filed the patent application on August 22, 2000 as a continuation of a previous

Page 1393

application for U.S. Patent No. 6,109,241, which was filed on January 26, 1999. He has sworn he invented the patent's subject matter on February 14, 1998. The Engelgau patent discloses an adjustable electronic pedal described in the specification as a "simplified vehicle control pedal assembly that is less expensive, and which uses fewer parts and is easier to package within the vehicle." Engelgau, col. 2, lines 2–5, Supplemental App. 6. Claim 4 of the patent, at issue here, describes:

> "A vehicle control pedal apparatus comprising:
>
> a support adapted to be mounted to a vehicle structure;
>
> an adjustable pedal assembly having a pedal arm moveable in for[e] and aft directions with respect to said support;
>
> a pivot for pivotally supporting said adjustable pedal assembly with respect to said support and defining a pivot axis; and
>
> an electronic control attached to said support for controlling a vehicle system;
>
> said apparatus characterized by said electronic control being responsive to said pivot for providing a signal that corresponds to pedal arm position as said pedal arm pivots about

> said pivot axis between rest and applied positions wherein the position of said pivot remains constant while said pedal arm moves in fore and aft directions with respect to said pivot." *Id.,* col. 6, lines 17–36, Supplemental App. 8 (diagram numbers omitted).

We agree with the District Court that the claim discloses "a position-adjustable pedal assembly with an electronic pedal position sensor attached to the support member of the pedal assembly. Attaching the sensor to the support member allows the sensor to remain in a fixed position while the driver adjusts the pedal." 298 F.Supp.2d, at 586–587.

Before issuing the Engelgau patent the U.S. Patent and Trademark Office (PTO) rejected one of the patent claims that was similar to, but broader than, the present claim 4. The claim did not include the requirement that the sensor be placed on a fixed pivot point. The PTO concluded the claim was an obvious combination of the prior art disclosed in Redding and Smith, explaining:

> " 'Since the prior ar[t] references are from the field of endeavor, the purpose disclosed ... would have been recognized in the pertinent art of Redding. Therefore it would have been obvious ... to provide the device of Redding with the ... means attached to a support member as taught by Smith.' " *Id.*, at 595.

In other words Redding provided an example of an adjustable pedal and Smith explained how to mount a sensor on a pedal's support structure, and the rejected patent claim merely put these two teachings together.

Although the broader claim was rejected, claim 4 was later allowed because it included the limitation of a fixed pivot point, which distinguished the design from Redding's. *Ibid.* Engelgau had not included Asano among the prior art references, and Asano was not mentioned in the patent's prosecution. Thus, the PTO did not have before it an adjustable pedal with a fixed pivot point. The patent issued on May 29, 2001 and was assigned to Teleflex.

Upon learning of KSR's design for GM, Teleflex sent a warning letter informing KSR that its proposal would violate the Engelgau patent. " 'Teleflex believes that any supplier of a product that combines an adjustable pedal with an electronic throttle control necessarily employs technology covered by one or more' " of Teleflex's patents. *Id.*, at 585. KSR refused to enter a royalty arrangement with Teleflex; so Teleflex sued for infringement, asserting KSR's pedal infringed the Engelgau patent and two other patents. *Ibid.* Teleflex later abandoned its claims regarding the other patents and dedicated the patents to the public. The remaining contention was that KSR's pedal system for GM infringed claim 4 of the Engelgau patent. Teleflex has not argued that the other three claims of the patent are infringed by KSR's pedal, nor has Teleflex argued that the mechanical adjustable pedal designed by KSR for Ford infringed any of its patents.

C

The District Court granted summary judgment in KSR's favor. After reviewing the pertinent history of pedal design, the scope of the Engelgau patent, and the relevant prior art, the court considered the validity of the contested claim. By direction of 35 U.S.C. §282, an issued patent is presumed valid. The District Court applied *Graham*'s framework to determine

Page 1394

whether under summary-judgment standards KSR had overcome the presumption and demonstrated that claim 4 was obvious in light of the prior art in existence when the claimed subject matter was invented. See §102(a).

The District Court determined, in light of the expert testimony and the parties' stipulations, that the level of ordinary skill in pedal design was " 'an undergraduate degree in mechanical engineering (or an equivalent amount of industry experience) [and] familiarity with pedal control systems for vehicles.' " 298 F.Supp.2d, at 590. The court then set forth the relevant prior art, including the patents and pedal designs described above.

Following *Graham*'s direction, the court compared the teachings of the prior art to the claims of Engelgau. It found "little difference." 298 F.Supp.2d, at 590. Asano taught everything contained in claim 4 except the use of a sensor to detect the pedal's position and transmit it to the computer controlling the throttle. That additional aspect was revealed in sources such as the '068 patent and the sensors used by Chevrolet.

Under the controlling cases from the Court of Appeals for the Federal Circuit, however, the District Court was not permitted to stop there. The court was required also to apply the TSM test. The District Court held KSR had satisfied the test. It reasoned (1) the state of the industry would lead inevitably to combinations of electronic sensors and adjustable pedals, (2) Rixon provided the basis for these developments, and (3) Smith taught a solution to the wire chafing problems in Rixon, namely locating the sensor on the fixed structure of the pedal. This could lead to the combination of Asano, or a pedal like it, with a pedal position sensor.

The conclusion that the Engelgau design was obvious was supported, in the District Court's view, by the PTO's rejection of the broader version of claim 4. Had Engelgau included Asano in his patent application, it reasoned, the PTO would have found claim 4 to be an obvious combination of Asano and Smith, as it had found the broader version an obvious combination of Redding and Smith. As a final matter, the District Court held that the secondary factor of Teleflex's commercial success with pedals based on Engelgau's design did not alter its conclusion. The District Court

granted summary judgment for KSR.

With principal reliance on the TSM test, the Court of Appeals reversed. It ruled the District Court had not been strict enough in applying the test, having failed to make " 'finding[s] as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of [the] invention' ... to attach an electronic control to the support bracket of the Asano assembly." 119 Fed. Appx., at 288 (brackets in original) (quoting *In re Kotzab*, 217 F.3d 1365, 1371 [55 USPQ2d 1313] (CA Fed. 2000)). The Court of Appeals held that the District Court was incorrect that the nature of the problem to be solved satisfied this requirement because unless the "prior art references address[ed] the precise problem that the patentee was trying to solve," the problem would not motivate an inventor to look at those references. 119 Fed. Appx., at 288.

Here, the Court of Appeals found, the Asano pedal was designed to solve the " 'constant ratio problem' "—that is, to ensure that the force required to depress the pedal is the same no matter how the pedal is adjusted—whereas Engelgau sought to provide a simpler, smaller, cheaper adjustable electronic pedal. *Ibid.* As for Rixon, the court explained, that pedal suffered from the problem of wire chafing but was not designed to solve it. In the court's view Rixon did not teach anything helpful to Engelgau's purpose. Smith, in turn, did not relate to adjustable pedals and did not "necessarily go to the issue of motivation to attach the electronic control on the support bracket of the pedal assembly." *Ibid.* When the patents were interpreted in this way, the Court of Appeals held, they would not have led a person of ordinary skill to put a sensor on the sort of pedal described in Asano.

That it might have been obvious to try the combination of Asano and a sensor was likewise irrelevant, in the court's view, because " ' "[o]bvious to try" has long been held not to constitute obviousness.' " *Id.*, at 289 (quoting *In re Deuel*, 51 F.3d 1552, 1559 [34 USPQ2d 1210] (CA Fed. 1995)).

The Court of Appeals also faulted the District Court's consideration of the PTO's rejection of the broader version of claim 4. The District Court's role, the Court of Appeals explained, was not to speculate regarding what the PTO might have done had the Engelgau patent mentioned Asano. Rather, the court held, the District Court was obliged first to

Page 1395

presume that the issued patent was valid and then to render its own independent judgment of obviousness based on a review of the prior art. The fact that the PTO had rejected the broader version of claim 4, the Court of Appeals said, had no place in that analysis.

The Court of Appeals further held that genuine issues of material fact precluded summary judgment. Teleflex had proffered statements from one expert that claim 4 " 'was a simple, elegant, and novel combination of features,' " 119 Fed. Appx., at 290, compared to Rixon, and from another expert that claim 4 was nonobvious because, unlike in Rixon, the sensor was mounted on the support bracket rather than the pedal itself. This evidence, the court concluded, sufficed to require a trial.

II

A

[1] We begin by rejecting the rigid approach of the Court of Appeals. Throughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here. To be sure, *Graham* recognized the need for "uniformity and definiteness." 383 U.S., at 18. Yet the principles laid down in *Graham* reaffirmed the "functional approach" of *Hotchkiss*, 11 How. 248. See 383 U.S., at 12. To this end, *Graham* set forth a broad inquiry and invited courts, where appropriate, to look at any secondary considerations that would prove instructive. *Id.*, at 17.

Neither the enactment of §103 nor the analysis in *Graham* disturbed this Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art. For over a half century, the Court has held that a "patent for a combination which only unites old elements with no change in their respective functions ... obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." *Great Atlantic & Pacific Tea Co.* v. *Supermarket Equipment Corp.*, 340 U.S. 147, 152 [87 USPQ 303] (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. Three cases decided after *Graham* illustrate the application of this doctrine.

In *United States* v. *Adams*, 383 U.S. 39, 40 [148 USPQ 479] (1966), a companion case to *Graham*, the Court considered the obviousness of a "wet battery" that varied from prior designs in two ways: It contained water, rather than the acids conventionally employed in storage batteries; and its electrodes were magnesium and cuprous chloride, rather than zinc and silver chloride. The Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. 383 U.S., at 50–51. It nevertheless rejected the Government's claim that Adams's battery was obvious. The Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *Id.*, at 51–52. When Adams designed his battery, the prior art warned that risks were involved in using the types of electrodes he employed. The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams's design was not obvious to those skilled in the art.

In *Anderson's-Black Rock, Inc.* v. *Pavement Salvage Co.*, 396 U.S. 57 [163 USPQ 673] (1969), the Court elaborated on this approach. The subject matter of the patent before the Court was a device combining two pre-existing elements: a radiant-heat burner and a paving machine. The device, the Court concluded, did not create some new synergy: The radiant-heat burner functioned just as a burner was expected to function; and the paving machine did the same. The two in combination did no more than they would in separate, sequential operation. *Id.*, at 60–62. In those circumstances, "while the combination of old elements performed a useful function, it added nothing to the nature and quality of the radiant-heat burner already patented," and the patent failed under §103. *Id.*, at 62 (footnote omitted).

Finally, in *Sakraida* v. *AG Pro, Inc.*, 425 U.S. 273 [189 USPQ 449] (1976), the Court derived from the precedents the conclusion that when a patent "simply arranges old elements with each performing the same function it had been known to perform" and yields no

Page 1396

more than one would expect from such an arrangement, the combination is obvious. *Id.*, at 282.

[2] The principles underlying these cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida* and *Anderson's-Black Rock* are illustrative—a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

[3] Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 [78 USPQ2d 1329] (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

B

[4] When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. See *Application of Bergel,* 292 F.2d 955, 956–957 [130 USPQ 206] (1961). As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

In the years since the Court of Customs and Patent Appeals set forth the essence of the TSM test, the Court of Appeals no doubt has applied the test in accord with these principles in many cases. There is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis. But when a court transforms the general principle into a

Page 1397

rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.

C

The flaws in the analysis of the Court of Appeals relate for the most part to the court's narrow conception of the obviousness inquiry reflected in its application of the TSM test. In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under §103. One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims.

[5] The first error of the Court of Appeals in this case was to foreclose this reasoning by holding that courts and patent examiners should look only to the problem the patentee was trying to solve. 119 Fed. Appx., at 288. The Court of Appeals failed to recognize that the problem motivating the patentee may be only one of many addressed by the patent's subject matter. The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art. Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

The second error of the Court of Appeals lay in its assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem. *Ibid.* The primary purpose of Asano was solving the constant ratio problem; so, the court concluded, an inventor considering how to put a sensor on an adjustable pedal would have no reason to consider putting it on the Asano pedal. *Ibid.* Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. Regardless of Asano's primary purpose, the design provided an obvious example of an adjustable pedal with a fixed pivot point; and the prior art was replete with patents indicating that a fixed pivot point was an ideal mount for a sensor. The idea that a designer hoping to make an adjustable electronic pedal would ignore Asano because Asano was designed to solve the constant ratio problem makes little sense. A person of ordinary skill is also a person of ordinary creativity, not an automaton.

[6] The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." *Id.*, at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.

The Court of Appeals, finally, drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. See *Graham*, 383 U.S., at 36 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to " 'guard against slipping into the use of hindsight' " (quoting *Monroe Auto Equipment Co.* v. *Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 [141 USPQ 549] (CA6 1964))). Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.

We note the Court of Appeals has since elaborated a broader conception of the TSM test than was applied in the instant matter. See, *e.g., DyStar Textilfarben GmbH & Co. Deutschland KG* v. *C. H. Patrick Co.*, 464 F.3d 1356, 1367 [80 USPQ2d 1641] (2006) ("Our suggestion test is in actuality quite flexible and not only permits, but *requires*, consideration of common knowledge and common sense"); *Alza Corp.* v. *Mylan Labs., Inc.*, 464 F.3d 1286, 1291 [80 USPQ2d 1001] (2006) ("There is flexibility in our obviousness jurisprudence because a motivation may be found *implicitly* in the prior art. We do not

Page 1398

have a rigid test that requires an actual teaching to combine ..."). Those decisions, of course, are not now before us and do not correct the errors of law made by the Court of Appeals in this case. The extent to which they may describe an analysis more consistent with our earlier precedents and our decision here is a matter for the Court of Appeals to consider in its future cases. What we hold is that the fundamental misunderstandings identified above led the Court of Appeals in this case to apply a test inconsistent with our patent law decisions.

III

When we apply the standards we have explained to the instant facts, claim 4 must be found obvious. We agree with and adopt the District Court's recitation of the relevant prior art and its determination of the level of ordinary skill in the field. As did the District Court, we see little difference between the teachings of Asano and Smith and the adjustable electronic pedal disclosed in claim 4 of the Engelgau patent. A person having ordinary skill in the art could have combined Asano with a pedal position sensor in a fashion encompassed by claim 4, and would have seen the benefits of doing so.

A

Teleflex argues in passing that the Asano pedal cannot be combined with a sensor in the manner described by claim 4 because of the design of Asano's pivot mechanisms. See Brief for Respondents 48–49, and n. 17. Therefore, Teleflex reasons, even if adding a sensor to Asano was obvious, that does not establish that claim 4 encompasses obvious subject matter. This argument was not, however, raised before the District Court. There Teleflex was content to assert only that the problem motivating the invention claimed by the Engelgau patent would not lead to the solution of combining of Asano with a sensor. See Teleflex's Response to KSR's Motion for Summary Judgment of Invalidity in No. 02–74586 (ED Mich.), pp. 18–20, App. 144a–146a. It is also unclear whether the current argument was raised before the Court of Appeals, where Teleflex advanced the nonspecific, conclusory contention that combining Asano with a sensor would not satisfy the limitations of claim 4. See Brief for Plaintiffs-Appellants in No. 04–1152 (CA Fed.), pp. 42–44. Teleflex's own expert declarations, moreover, do not support the point Teleflex now raises. See Declaration of Clark J. Radcliffe, Ph.D., Supplemental App. 204–207; Declaration of Timothy L. Andresen, *id.*, at 208–210. The only statement in either declaration that might bear on the argument is found in the Radcliffe declaration:

> "Asano ... and Rixon ... are complex mechanical linkage-based devices that are expensive to produce and assemble and difficult to package. It is exactly these difficulties with prior art designs that [Engelgau] resolves. The use of an adjustable pedal with a single pivot reflecting pedal position combined with an electronic control mounted between the support and the adjustment assembly at that pivot was a simple, elegant, and novel combination of features in the Engelgau '565 patent." *Id.*, at 206, ¶16.

Read in the context of the declaration as a whole this is best interpreted to mean that Asano could not be used to solve "[t]he problem addressed by Engelgau '565[:] to provide a less expensive, more quickly assembled, and smaller package adjustable pedal assembly with electronic control." *Id.*, at 205, ¶10.

The District Court found that combining Asano with a pivot-mounted pedal position sensor fell within the scope of claim 4. 298 F.Supp.2d, at 592–593. Given the sigificance of that finding to the District Court's judgment, it is apparent that Teleflex would have made clearer challenges to it if it intended to preserve this claim. In light of Teleflex's failure to raise the argument in a clear fashion, and the silence of the Court of Appeals on the issue, we take the District Court's conclusion on the point to be correct.

B

[7] The District Court was correct to conclude that, as of the time Engelgau designed the subject matter in claim 4, it was obvious to a person of ordinary skill to combine Asano with a pivot-mounted pedal position sensor. There then existed a marketplace that created a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for achieving this advance. The Court of Appeals considered the issue too narrowly by, in effect, asking whether a pedal designer writing on a blank slate would have chosen both Asano and a

Page 1399

modular sensor similar to the ones used in the Chevrolet truckline and disclosed in the '068 patent. The District Court employed this narrow inquiry as well, though it reached the correct result nevertheless. The proper question to have asked was whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading Asano with a sensor.

In automotive design, as in many other fields, the interaction of multiple components means that changing one component often requires the others to be modified as well. Technological developments made it clear that engines using computer-controlled throttles would become standard. As a result, designers might have decided to design new pedals from scratch; but they also would have had reason to make pre-existing pedals work with the new engines. Indeed, upgrading its own pre-existing model led KSR to design the pedal now accused of infringing the Engelgau patent.

For a designer starting with Asano, the question was where to attach the sensor. The consequent legal question, then, is whether a pedal designer of ordinary skill starting with Asano would have found it obvious to put the sensor on a fixed pivot point. The prior art discussed above leads us to the conclusion that attaching the sensor where both KSR and Engelgau put it would have been obvious to a person of ordinary skill.

The '936 patent taught the utility of putting the sensor on the pedal device, not in the engine. Smith, in turn, explained to put the sensor not on the pedal's footpad but instead on its support structure. And from the known wire-chafing problems of Rixon, and Smith's teaching that "the pedal assemblies must not precipitate any motion in the connecting wires," Smith, col. 1, lines 35–37, Supplemental App. 274, the designer would know to place the sensor on a nonmoving part of the pedal structure. The most obvious nonmoving point on the structure from which a sensor can easily detect the pedal's position is a pivot point. The designer, accordingly, would follow Smith in mounting the sensor on a pivot, thereby designing an adjustable electronic pedal covered by claim 4.

Just as it was possible to begin with the objective to upgrade Asano to work with a computer-controlled throttle, so too was it possible to take an adjustable electronic pedal like Rixon and seek an improvement that would avoid the wire-chafing problem. Following similar steps to those just explained, a designer would learn from Smith to avoid sensor movement and would come, thereby, to Asano because Asano disclosed an adjustable pedal with a fixed pivot.

Teleflex indirectly argues that the prior art taught away from attaching a sensor to Asano because Asano in its view is bulky, complex, and expensive. The only evidence Teleflex marshals in support of this argument, however, is the Radcliffe declaration, which merely indicates that Asano would not have solved Engelgau's goal of making a small, simple, and inexpensive pedal. What the declaration does not indicate is that Asano was somehow so flawed that there was no reason to upgrade it, or pedals like it, to be compatible with modern engines. Indeed, Teleflex's own declarations refute this conclusion. Dr. Radcliffe states that Rixon suffered from the same bulk and complexity as did Asano. See *id.*, at 206. Teleflex's other expert, however, explained that Rixon was itself designed by adding a sensor to a pre-existing mechanical pedal. See *id.*, at 209. If Rixon's base pedal was not too flawed to upgrade, then Dr. Radcliffe's declaration does not show Asano was either. Teleflex may have made a plausible argument that Asano is inefficient as compared to Engelgau's preferred embodiment, but to judge Asano against Engelgau would be to engage in the very hindsight bias Teleflex rightly urges must be avoided. Accordingly, Teleflex has not shown anything in the prior art that taught away from the use of Asano.

Like the District Court, finally, we conclude Teleflex has shown no secondary factors to dislodge the determination that claim 4 is obvious. Proper application of *Graham* and our other precedents to these facts therefore leads to the conclusion that claim 4 encompassed obvious subject matter. As a result, the claim fails to meet the requirement of §103.

We need not reach the question whether the failure to disclose Asano during the prosecution of Engelgau voids the presumption of validity given to issued patents, for claim 4 is obvious despite the presumption. We nevertheless think it appropriate to note that the rationale underlying the presumption—that the PTO, in its expertise, has approved the claim—seems much diminished here.

Page 1400

IV

[8] A separate ground the Court of Appeals gave for reversing the order for summary judgment was the existence of a dispute over an issue of material fact. We disagree with the Court of Appeals on this point as well. To the extent the court understood the *Graham* approach to exclude the possibility of summary judgment when an expert provides a conclusory affidavit addressing the question of obviousness, it misunderstood the role expert testimony plays in the analysis. In considering summary judgment on that question the district court can and should take into account expert testimony, which may resolve or keep open certain questions of fact. That is not the end of the issue, however. The ultimate judgment of obviousness is a legal determination. *Graham*, 383 U.S., at 17. Where, as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors, summary judgment is appropriate. Nothing in the declarations proffered by Teleflex prevented the District Court from reaching the careful conclusions underlying its order for summary judgment in this case.

* * *

We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts. See U.S. Const., Art. I, §8, cl. 8. These premises led to the bar on patents claiming obvious subject matter established in *Hotchkiss* and codified in §103. Application of the bar must not be confined within a test or formulation too constrained to serve its purpose.

KSR provided convincing evidence that mounting a modular sensor on a fixed pivot point of the Asano pedal was a design step well within the grasp of a person of ordinary skill in the relevant art. Its arguments, and the record, demonstrate that claim 4 of the Engelgau patent is obvious. In rejecting the District Court's rulings, the Court of Appeals analyzed the issue in a narrow, rigid manner inconsistent with §103 and our precedents. The judgment of the Court of Appeals is reversed, and the case remanded for further proceedings consistent with this opinion.

It is so ordered.

- End of Case -

EXHIBIT 10

(8) Narrow woven ribbons comprised at least 85 percent by weight of threads having a denier of 225 or higher;

(9) Narrow woven ribbons constructed from pile fabrics (*i.e.*, fabrics with a surface effect formed by tufts or loops of yarn that stand up from the body of the fabric);

(10) Narrow woven ribbon affixed (including by tying) as a decorative detail to non-subject merchandise, such as a gift bag, gift box, gift tin, greeting card or plush toy, or affixed (including by tying) as a decorative detail to packaging containing non-subject merchandise;

(11) Narrow woven ribbon that is (a) affixed to non-subject merchandise as a working component of such non-subject merchandise, such as where narrow woven ribbon comprises an apparel trimming, book marker, bag cinch, or part of an identity card holder, or (b) affixed (including by tying) to non-subject merchandise as a working component that holds or packages such non-subject merchandise or attaches packaging or labeling to such non-subject merchandise, such as a "belly band" around a pair of pajamas, a pair of socks or a blanket;

(12) Narrow woven ribbon(s) comprising a belt attached to and imported with an item of wearing apparel, whether or not such belt is removable from such item of wearing apparel; and

(13) Narrow woven ribbon(s) included with non-subject merchandise in kits, such as a holiday ornament craft kit or a scrapbook kit, in which the individual lengths of narrow woven ribbon(s) included in the kit are each no greater than eight inches, the aggregate amount of narrow woven ribbon(s) included in the kit does not exceed 48 linear inches, none of the narrow woven ribbon(s) included in the kit is on a spool, and the narrow woven ribbon(s) is only one of multiple items included in the kit.

The merchandise subject to this order is classifiable under the HTSUS statistical categories 5806.32.1020; 5806.32.1030; 5806.32.1050 and 5806.32.1060. Subject merchandise also may enter under subheadings 5806.31.00; 5806.32.20; 5806.39.20; 5806.39.30; 5808.90.00; 5810.91.00; 5810.99.90; 5903.90.10; 5903.90.25; 5907.00.60; and 5907.00.80 and under statistical categories 5806.32.1080; 5810.92.9080; 5903.90.3090; and 6307.90.9889. The HTSUS statistical categories and subheadings are provided for convenience and customs purposes; however, the written description of the merchandise under the order is dispositive.

Countervailing Duty Order

According to section 706(b)(2) of the Act, duties shall be assessed on subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the ITC's notice of final determination if that determination is based upon the threat of material injury. Section 706(b)(1) of the Act states, "If the Commission, in its final determination under section 705(b), finds material injury or threat of material injury which, but for the suspension of liquidation under section 703(d)(2), would have led to a finding of material injury, then entries of the merchandise subject to the countervailing duty order, the liquidation of which has been suspended under section 703(d)(2), shall be subject to the imposition of countervailing duties under section 701(a)." In addition, section 706(b)(2) of the Act requires CBP to refund any cash deposits or bonds of estimated countervailing duties posted since the Department's preliminary countervailing duty determination, if the ITC's final determination is threat-based. Because the ITC's final determination in this case is based on the threat of material injury and is not accompanied by a finding that injury would have resulted but for the imposition of suspension of liquidation of entries since the Department's *Preliminary Determination*[1] was published in the **Federal Register**, section 706(b)(2) of the Act is applicable.

As a result of the ITC's determination, and in accordance with section 706(a)(1) of the Act, the Department will direct U.S. Customs and Border Protection ("CBP") to assess, upon further instruction by the Department, countervailing duties equal to the amount of the net countervailable subsidy for all relevant entries of narrow woven ribbons from the PRC. In accordance with section 706 of the Act, the Department will direct CBP to reinstitute suspension of liquidation[2] effective on the date of publication of the ITC's notice of final determination in the **Federal Register**, and to require a cash deposit for each entry of subject merchandise in an amount equal to the net countervailable subsidy rates noted below.

Exporter/manufacturer	Net subsidy rate
Yama Ribbons and Bows Co., Ltd	1.56
Changtai Rongshu Textile Co., Ltd	117.95
All Others	1.56

Termination of the Suspension of Liquidation

The Department will also instruct CBP to terminate the suspension of liquidation for entries of narrow woven ribbons from the PRC entered, or withdrawn from warehouse, for consumption prior to the publication of the ITC's notice of final determination, and refund any cash deposits made and release any bonds posted between December 14, 2009 (*i.e.*, the date of publication of the Department's *Preliminary Determination*) and the date of publication of the ITC's final determination in the **Federal Register**.

This notice constitutes the countervailing duty order with respect to narrow woven ribbons from the PRC, pursuant to section 706(a) of the Act. Interested parties may contact the Department's Central Records Unit, Room 1117 of the main Commerce Building, for copies of an updated list of countervailing duty orders currently in effect.

This order is issued and published in accordance with section 706(a) of the Act and 19 CFR 351.211(b).

Dated: August 30, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010–21978 Filed 8–31–10; 8:45 am]

BILLING CODE 3510–DS–P

[1] *Narrow Woven Ribbons With Woven Selvedge From the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Countervailing Duty Determination With Final Antidumping Duty Determination*, 74 FR 66090 (December 14, 2009).

[2] The Department instructed CBP to discontinue the suspension of liquidation on April 13, 2010, in accordance with section 703(d) of the Act. Section 703(d) states that the suspension of liquidation pursuant to a preliminary determination may not remain in effect for more than four months.

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO–P–2010–0055]

Examination Guidelines Update: Developments in the Obviousness Inquiry After KSR v.Teleflex

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is issuing an update (*2010 KSR Guidelines Update*) to its obviousness guidelines for its personnel to be used when applying the law of obviousness under

35 U.S.C. 103. This *2010 KSR Guidelines Update* highlights case law developments on obviousness under 35 U.S.C. 103 since the 2007 decision by the United States Supreme Court (Supreme Court) in *KSR Int'l Co.* v. *Teleflex Inc.* These guidelines are intended to be used by Office personnel in conjunction with the guidance in the Manual of Patent Examining Procedure when applying the law of obviousness under 35 U.S.C. 103. Members of the public are invited to provide comments on the *2010 KSR Guidelines Update.* The Office is especially interested in receiving suggestions of recent decisional law in the field of obviousness that would have particular value as teaching tools.

DATES: *Effective Date:* This *2010 KSR Guidelines Update* is effective September 1, 2010.

ADDRESSES: Comments concerning this *2010 KSR Guidelines Update* may be sent by electronic mail message over the Internet addressed to *KSR_Guidance@uspto.gov,* or submitted by mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450. Although comments may be submitted by mail, the Office prefers to receive comments via the Internet.

FOR FURTHER INFORMATION CONTACT: Kathleen Kahler Fonda or Pinchus M. Laufer, Legal Advisors, Office of Patent Legal Administration, Office of the Associate Commissioner for Patent Examination Policy, by telephone at (571) 272–7754 or (571) 272–7726; by mail addressed to: Mail Stop Comments Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450; or by facsimile transmission to (571) 273–7754, marked to the attention of Kathleen Kahler Fonda.

SUPPLEMENTARY INFORMATION:

1. *Introduction.* The purpose of this *2010 KSR Guidelines Update* is to remind Office personnel of the principles of obviousness explained by the Supreme Court in *KSR Int'l Co.* v. *Teleflex Inc.,* 550 U.S 398 (2007) (*KSR*), and to provide additional guidance in view of decisions by the United States Court of Appeals for the Federal Circuit (Federal Circuit) since *KSR.* This body of case law developed over the past three years provides additional examples that will be useful to Office personnel as well as practitioners during the examination process. Although every question of obviousness must be decided on its own facts, these cases begin to clarify the contours of the obviousness inquiry after *KSR,* and help to show when a rejection on this basis is proper and when it is not.

This *2010 KSR Guidelines Update* does not constitute substantive rule making and hence does not have the force and effect of law. It has been developed as a matter of internal Office management and is not intended to create any right or benefit, substantive or procedural, enforceable by any party against the Office. Rejections will continue to be based upon the substantive law, and it is these rejections that are appealable. Consequently, any failure by Office personnel to follow this *2010 KSR Guidelines Update* is neither appealable nor petitionable.

After a review of the principles of obviousness and Office policy as reflected in the *Manual of Patent Examining Procedure* (MPEP), this *2010 KSR Guidelines Update* addresses a number of issues that arise when Office personnel consider whether or not a claimed invention is obvious. The concepts discussed are grounded in Federal Circuit cases, and correlated with existing Office policy as appropriate. A number of cases which have been selected for their instructional value on the issue of obviousness will be discussed in detail.

The law of obviousness will continue to be refined, and Office personnel are encouraged to maintain an awareness of precedential case law from the Federal Circuit and precedential decisions of the Board of Patent Appeals and Interferences (Board) in this area. The Office will train Office personnel and update the MPEP as necessary to reflect the current state of the law.

2. *Principles of Obviousness and the Guidelines.* In response to the Supreme Court's April 2007 decision in *KSR,* the Office developed guidelines for patent examiners to follow when determining obviousness of a claimed invention and published these guidelines in the **Federal Register** and Official Gazette. *See Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co.* v. *Teleflex Inc.,* 72 FR 57526 (Oct. 10, 2007), 1324 *Off. Gaz. Pat. Office* 23 (Nov. 6, 2007) (*2007 KSR Guidelines*). The *2007 KSR Guidelines* have been incorporated in the MPEP. *See* MPEP § 2141 (8th ed. 2001) (Rev. 6, Sept. 2007). The purpose of the *2007 KSR Guidelines* was to give Office personnel practical guidance on how to evaluate obviousness issues under 35 U.S.C. 103(a) in accordance with the Supreme Court's instruction in *KSR.* The *2007 KSR Guidelines* also alerted Office personnel to the importance of considering rebuttal evidence submitted by patent applicants in response to obviousness rejections.

The *2007 KSR Guidelines* pointed out, as had the Supreme Court in *KSR,* that the factual inquiries announced in *Graham* v. *John Deere,* 383 U.S. 1, 17–18 (1966) (scope and content of the prior art; differences between the claimed invention and the prior art; level of ordinary skill in the art; and secondary indicia of nonobviousness), remain the foundation of any determination of obviousness. It remains true that "[t]he determination of obviousness is dependent on the facts of each case." *Sanofi-Synthelabo* v. *Apotex, Inc.,* 550 F.3d 1075, 1089 (Fed. Cir. 2008) (citing *Graham,* 383 U.S. at 17–18 (1966)). As for the reasoning required to support an obviousness determination, the *2007 KSR Guidelines* noted that the teaching-suggestion-motivation (TSM) test was but one possible approach. The *2007 KSR Guidelines* identified six other rationales gleaned from the *KSR* decision as examples of appropriate lines of reasoning that could also be used. The six other rationales identified in the *2007 KSR Guidelines* are: (1) Combining prior art elements according to known methods to yield predictable results; (2) simple substitution of one known element for another to obtain predictable results; (3) use of a known technique to improve similar devices, methods, or products in the same way; (4) applying a known technique to a known device, method, or product ready for improvement to yield predictable results; (5) obvious to try—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and (6) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art. Any rationale employed must provide a link between the factual findings and the legal conclusion of obviousness.

It is important for Office personnel to recognize that when they do choose to formulate an obviousness rejection using one of the rationales suggested by the Supreme Court in *KSR* and discussed in the *2007 KSR Guidelines,* they are to adhere to the instructions provided in the MPEP regarding the necessary factual findings. However, the *2007 KSR Guidelines* also stressed that while the *Graham* inquiries and the associated reasoning are crucial to a proper obviousness determination, the Supreme Court in *KSR* did not place any limit on the particular approach to be taken to formulate the line of reasoning.

In other words, the *KSR* decision is not to be seen as replacing a single test for obviousness—the TSM test—with the seven rationales listed in the *2007 KSR Guidelines*. *See* MPEP §§ 2141 and 2143 (8th ed. 2001) (Rev. 8, July 2010) (references to the MPEP are to Revision 8 of the 8th Edition of the MPEP unless otherwise indicated). It remains Office policy that appropriate factual findings are required in order to apply the enumerated rationales properly. If a rejection has been made that omits one of the required factual findings, and in response to the rejection a practitioner or inventor points out the omission, Office personnel must either withdraw the rejection, or repeat the rejection including all required factual findings.

3. *The Impact of the KSR Decision.* *KSR*'s renewed emphasis on the foundational principles of *Graham* coupled with its abrogation of the strict TSM test have clearly impacted the manner in which Office personnel and practitioners carry out the business of prosecuting patent applications with regard to issues of obviousness. However, Office personnel as well as practitioners should also recognize the significant extent to which the obviousness inquiry has remained constant in the aftermath of *KSR*.

In footnote 2 of the *2007 KSR Guidelines*, the Office acknowledged that ongoing developments in the law of obviousness were to be expected in the wake of the *KSR* decision. That footnote also stated that it was "not clear which Federal Circuit decisions will retain their viability" after *KSR*. See *2007 KSR Guidelines*, 72 FR at 57,528 n.2. The edition of the MPEP that was current when the *KSR* decision was handed down had made the following statement in § 2144:

> The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law.

MPEP § 2144 (8th ed. 2001) (Rev. 5, Aug. 2006) (citing five pre-*KSR* Federal Circuit opinions and two decisions of the Board). The *KSR* decision has reinforced those earlier decisions that validated a more flexible approach to providing reasons for obviousness. However, the Supreme Court's pronouncement in *KSR* has at the same time clearly undermined the continued viability of cases such as *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002), insofar as *Lee* appears to require a strict basis in record evidence as a reason to modify the prior art.

The Supreme Court's flexible approach to the obviousness inquiry is reflected in numerous pre-*KSR* decisions, as can be seen in a review of MPEP § 2144. This section provides many lines of reasoning to support a determination of obviousness based upon earlier legal precedent that had condoned the use of particular examples of what may be considered common sense or ordinary routine practice (*e.g.*, making integral, changes in shape, making adjustable). Thus, the type of reasoning sanctioned by the opinion in *KSR* has long been a part of the patent examination process. *See* MPEP § 2144.

Although the *KSR* approach is flexible with regard to the line of reasoning to be applied, the *2007 KSR Guidelines* and MPEP § 2143 state: "The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." MPEP § 2143. In *Ball Aerosol* v. *Limited Brands*, 555 F.3d 984 (Fed. Cir. 2009), the Federal Circuit offered additional instruction as to the need for an explicit analysis. The Federal Circuit explained, as is consistent with the *2007 KSR Guidelines*, that the Supreme Court's requirement for an explicit analysis does not require record evidence of an explicit teaching of a motivation to combine in the prior art.

> [T]he analysis that "should be made explicit" refers not to the teachings in the prior art of a motivation to combine, but to the court's analysis * * *. Under the flexible inquiry set forth by the Supreme Court, the district court therefore erred by failing to take account of "the inferences and creative steps," or even routine steps, that an inventor would employ and by failing to find a motivation to combine related pieces from the prior art.

Ball Aerosol, 555 F.3d at 993. The Federal Circuit's directive in *Ball Aerosol* was addressed to a lower court, but it applies to Office personnel as well. When setting forth a rejection, Office personnel are to continue to make appropriate findings of fact as explained in MPEP §§ 2141 and 2143, and must provide a reasoned explanation as to why the invention as claimed would have been obvious to a person of ordinary skill in the art at the time of the invention. This requirement for explanation remains even in situations in which Office personnel may properly rely on intangible realities such as common sense and ordinary ingenuity.

When considering obviousness, Office personnel are cautioned against treating any line of reasoning as a *per se* rule. MPEP § 2144 discusses supporting a rejection under 35 U.S.C. 103 by reliance on scientific theory and legal precedent. In keeping with the flexible approach and the requirement for explanation, Office personnel may invoke legal precedent as a source of supporting rationale when warranted and appropriately supported. *See* MPEP § 2144.04. So, for example, automating a manual activity, making portable, making separable, reversal or duplication of parts, or purifying an old product may form the basis of a rejection. However, such rationales should not be treated as *per se* rules, but rather must be explained and shown to apply to the facts at hand. A similar caveat applies to any obviousness analysis. Simply stating the principle (*e.g.*, "art recognized equivalent," "structural similarity") without providing an explanation of its applicability to the facts of the case at hand is generally not sufficient to establish a *prima facie* case of obviousness.

Many basic approaches that a practitioner may use to demonstrate nonobviousness also continue to apply in the post-*KSR* era. Since it is now clear that a strict TSM approach is not the only way to establish a *prima facie* case of obviousness, it is true that practitioners have been required to shift the emphasis of their nonobviousness arguments to a certain degree. However, familiar lines of argument still apply, including teaching away from the claimed invention by the prior art, lack of a reasonable expectation of success, and unexpected results. Indeed, they may have even taken on added importance in view of the recognition in *KSR* of a variety of possible rationales.

At the time the *KSR* decision was handed down, some observers questioned whether the principles discussed were intended by the Supreme Court to apply to all fields of inventive endeavor. Arguments were made that because the technology at issue in *KSR* involved the relatively well-developed and predictable field of vehicle pedal assemblies, the decision was relevant only to such fields. The Federal Circuit has soundly repudiated such a notion, stating that *KSR* applies across technologies:

> This court also declines to cabin *KSR* to the "predictable arts" (as opposed to the "unpredictable art" of biotechnology). In fact, this record shows that one of skill in this advanced art would find these claimed "results" profoundly "predictable."

In re Kubin, 561 F.3d 1351, 1360 (Fed. Cir. 2009). Thus, Office personnel should not withdraw any rejection solely on the basis that the invention lies in a technological area ordinarily considered to be unpredictable.

The decisions of the Federal Circuit discussed in this *2010 KSR Guidelines*

Update provide Office personnel as well as practitioners with additional examples of the law of obviousness. The purpose of the *2007 KSR Guidelines* was, as stated above, to help Office personnel to determine when a claimed invention is not obvious, and to provide an appropriate supporting rationale when an obviousness rejection is appropriate. Now that a body of case law is available to guide Office personnel and practitioners as to the boundaries between obviousness and nonobviousness, it is possible in this *2010 KSR Guidelines Update* to contrast situations in which the subject matter was found to have been obvious with those in which it was determined not to have been obvious. Thus, Office personnel may use this *2010 KSR Guidelines Update* in conjunction with the *2007 KSR Guidelines* (incorporated into MPEP §§ 2141 and 2143) to provide a more complete view of the state of the law of obviousness.

This *2010 KSR Guidelines Update* provides a "teaching point" for each discussed case. The "teaching point" may be used to quickly determine the relevance of the discussed case, but should not be used as a substitute for reading the remainder of the discussion of the case in this *2010 KSR Guidelines Update.* Nor should any case in this *2010 KSR Guidelines Update* be applied or cited in an Office action solely on the basis of what is stated in the "teaching point" for the case.

4. *Obviousness Examples from Federal Circuit Cases.* The impact of the Supreme Court's decision in *KSR* can be more readily understood in the context of factual scenarios. The cases in this *2010 KSR Guidelines Update* are broadly grouped according to obviousness concepts in order to provide persons involved with patent prosecution with ready access to the examples that are most pertinent to the issue at hand. The first three groups correspond directly with three of the rationales identified in the *2007 KSR Guidelines.* These rationales—combining prior art elements, substituting one known element for another, and obvious to try—have each been the subject of a significant number of post-*KSR* obviousness decisions. The fourth group focuses on issues concerning consideration of evidence during prosecution. Office personnel as well as practitioners are reminded of the technology-specific obviousness examples previously posted on the Office's Web site at *http://www.uspto.gov/web/offices/pac/dapp/opla/ksr/ksr_training_materials.htm.*

Although the other rationales discussed in the *2007 KSR Guidelines* are not the focus of separate discussions in this *2010 KSR Guidelines Update,* it will be noted that obviousness concepts such as applying known techniques, design choice, and market forces are addressed when they arise in the selected cases. The cases included in this *2010 KSR Guidelines Update* reinforce the idea, presented in the *2007 KSR Guidelines,* that there may be more than one line of reasoning that can properly be applied to a particular factual scenario. The selected decisions also illustrate the overlapping nature of the lines of reasoning that may be employed to establish a *prima facie* case of obviousness. Although the *2007 KSR Guidelines* presented the rationales as discrete, self-contained lines of reasoning, and they may indeed be employed that way, it is useful to recognize that real-world situations may require analyses that may not be so readily pigeon-holed into distinct categories.

A. *Combining Prior Art Elements.* In discussing the obviousness rationale concerning combining prior art elements, identified as Rationale A, the *2007 KSR Guidelines* quoted *KSR* and noted that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR,* 550 U.S. at 401. In view of the cases decided since *KSR,* one situation when it is important to identify a reason to combine known elements in a known manner to obtain predictable results is when the combination requires a greater expenditure of time, effort, or resources than the prior art teachings. Even though the components are known, the combining step is technically feasible, and the result is predictable, the claimed invention may nevertheless be nonobvious when the combining step involves such additional effort that no one of ordinary skill would have undertaken it without a recognized reason to do so. When a combination invention involves additional complexity as compared with the prior art, the invention may be nonobvious unless an examiner can articulate a reason for including the added features or steps. This is so even when the claimed invention could have been readily implemented.

Example 4.1. In re Omeprazole Patent Litigation, 536 F.3d 1361 (Fed. Cir. 2008). *Teaching point:* Even where a general method that could have been applied to make the claimed product was known and within the level of skill of the ordinary artisan, the claim may nevertheless be nonobvious if the problem which had suggested use of the method had been previously unknown.

The case of *In re Omeprazole Patent Litigation* is one in which the claims in question were found to be nonobvious in the context of an argument to combine prior art elements. The invention involved applying enteric coatings to a drug in pill form for the purpose of ensuring that the drug did not disintegrate before reaching its intended site of action. The drug at issue was omeprazole, the generic name for gastric acid inhibitor marketed as Prilosec®. The claimed formulation included two layers of coatings over the active ingredient.

The district court found that Astra's patent in suit was infringed by defendants Apotex and Impax. The district court rejected Apotex's defense that the patents were invalid for obviousness. Apotex had argued that the claimed invention was obvious because coated omeprazole tablets were known from a prior art reference, and because secondary subcoatings in pharmaceutical preparations generally were also known. There was no evidence of unpredictability associated with applying two different enteric coatings to omeprazole. However, Astra's reason for applying an intervening subcoating between the prior art coating and omeprazole had been that the prior art coating was actually interacting with omeprazole, thereby contributing to undesirable degradation of the active ingredient. This degradation of omeprazole by interaction with the prior art coating had not been recognized in the prior art. Therefore, the district court reasoned that based on the evidence available, a person of ordinary skill in the art would have had no reason to include a subcoating in an omeprazole pill formulation.

The Federal Circuit affirmed the district court's decision that the claimed invention was not obvious. Even though subcoatings for enteric drug formulation were known, and there was no evidence of undue technical hurdles or lack of a reasonable expectation of success, the formulation was nevertheless not obvious because the flaws in the prior art formulation that had prompted the modification had not been recognized. Thus there would have been no reason to modify the initial formulation, even though the modification could have been done. Moreover, a person of skill in the art likely would have chosen a different modification even if he or she had recognized the problem.

Office personnel should note that in this case the modification of the prior art that had been presented as an

argument for obviousness was an extra process step that added an additional component to a known, successfully marketed formulation. The proposed modification thus amounted to extra work and greater expense for no apparent reason. This is not the same as combining known prior art elements A and B when each would have been expected to contribute its own known properties to the final product. In the *Omeprazole* case, in view of the expectations of those of ordinary skill in the art, adding the subcoating would not have been expected to confer any particular desirable property on the final product. Rather, the final product obtained according to the proposed modifications would merely have been expected to have the same functional properties as the prior art product.

The *Omeprazole* case can also be analyzed in view of the discovery of a previously unknown problem by the patentee. If the adverse interaction between active agent and coating had been known, it might well have been obvious to use a subcoating. However, since the problem had not been previously known, there would have been no reason to incur additional time and expense to add another layer, even though the addition would have been technologically possible. This is true because the prior art of record failed to mention any stability problem, despite the acknowledgment during testimony at trial that there was a known theoretical reason that omeprazole might be subject to degradation in the presence of the known coating material.

Example 4.2. Crocs, Inc. v. *U.S. International Trade Commission,* 598 F.3d 1294 (Fed. Cir. 2010). *Teaching point:* A claimed combination of prior art elements may be nonobvious where the prior art teaches away from the claimed combination and the combination yields more than predictable results.

The case of *Crocs, Inc.* v. *U.S. International Trade Commission* is a decision in which the claimed foam footwear was held by the Federal Circuit to be nonobvious over a combination of prior art references.

The claims involved in the obviousness issue were from Crocs' U.S. Patent No. 6,993,858, and were drawn to footwear in which a one-piece molded foam base section formed the top of the shoe (the upper) and the sole. A strap also made of foam was attached to the foot opening of the upper, such that the strap could provide support to the Achilles portion of the wearer's foot. The strap was attached via connectors that allowed it to be in contact with the base section, and to pivot relative to the base section. Because both the base portion and the strap were made of foam, friction between the strap and the base section allowed the strap to maintain its position after pivoting. In other words, the foam strap did not fall under the force of gravity to a position adjacent to the heel of the base section.

The International Trade Commission (ITC) determined that the claims were obvious over the combination of two pieces of prior art. The first was the Aqua Clog, which was a shoe that corresponded to the base section of the footwear of the '858 patent. The second was the Aguerre patent, which taught heel straps made of elastic or another flexible material. In the ITC's view, the claimed invention was obvious because the prior art Aqua Clog differed from the claimed invention only as to the presence of the strap, and a suitable strap was taught by Aguerre.

The Federal Circuit disagreed. The Federal Circuit stated that the prior art did not teach foam heel straps, or that a foam heel strap should be placed in contact with a foam base. The Federal Circuit pointed out that the prior art actually counseled against using foam as a material for the heel strap of a shoe.

> The record shows that the prior art would actually discourage and teach away from the use of foam straps. An ordinary artisan in this field would not add a foam strap to the foam Aqua Clog because foam was likely to stretch and deform, in addition to causing discomfort for a wearer. The prior art depicts foam as unsuitable for straps.

Id. at 1309.

The Federal Circuit continued, stating that even if—contrary to fact—the claimed invention had been a combination of elements that were known in the prior art, the claims still would have been nonobvious. There was testimony in the record that the loose fit of the heel strap made the shoe more comfortable for the wearer than prior art shoes in which the heel strap was constantly in contact with the wearer's foot. In the claimed footwear, the foam heel strap contacted the wearer's foot only when needed to help reposition the foot properly in the shoe, thus reducing wearer discomfort that could arise from constant contact. This desirable feature was a result of the friction between the base section and the strap that kept the strap in place behind the Achilles portion of the wearer's foot. The Federal Circuit pointed out that this combination "yielded more than predictable results." *Id.* at 1310. Aguerre had taught that friction between the base section and the strap was a problem rather than an advantage, and had suggested the use of nylon washers to reduce friction. Thus the Federal Circuit stated that even if all elements of the claimed invention had been taught by the prior art, the claims would not have been obvious because the combination yielded more than predictable results.

The Federal Circuit's discussion in *Crocs* serves as a reminder to Office personnel that merely pointing to the presence of all claim elements in the prior art is not a complete statement of a rejection for obviousness. In accordance with MPEP § 2143 A(3), a proper rejection based on the rationale that the claimed invention is a combination of prior art elements also includes a finding that results flowing from the combination would have been predictable to a person of ordinary skill in the art. MPEP § 2143 A(3). If results would not have been predictable, Office personnel should not enter an obviousness rejection using the combination of prior art elements rationale, and should withdraw such a rejection if it has been made.

Example 4.3. Sundance, Inc. v. *DeMonte Fabricating Ltd.,* 550 F.3d 1356 (Fed. Cir. 2008). *Teaching point:* A claimed invention is likely to be obvious if it is a combination of known prior art elements that would reasonably have been expected to maintain their respective properties or functions after they have been combined.

Sundance involved a segmented and mechanized cover for trucks, swimming pools, or other structures. The claim was found to be obvious over the prior art applied.

A first prior art reference taught that a reason for making a segmented cover was ease of repair, in that a single damaged segment could be readily removed and replaced when necessary. A second prior art reference taught the advantages of a mechanized cover for ease of opening. The Federal Circuit noted that the segmentation aspect of the first reference and the mechanization function of the second perform in the same way after combination as they had before. The Federal Circuit further observed that a person of ordinary skill in the art would have expected that adding replaceable segments as taught by the first reference to the mechanized cover of the other would result in a cover that maintained the advantageous properties of both of the prior art covers.

Thus, the *Sundance* case points out that a hallmark of a proper obviousness rejection based on combining known prior art elements is that one of ordinary skill in the art would reasonably have expected the elements to maintain their respective properties or functions after they have been combined.

Example 4.4. Ecolab, Inc. v. *FMC Corp.*, 569 F.3d 1335 (Fed Cir. 2009). *Teaching point:* A combination of known elements would have been *prima facie* obvious if an ordinarily skilled artisan would have recognized an apparent reason to combine those elements and would have known how to do so.

In the case of *Ecolab, Inc.* v. *FMC Corp.*, an "apparent reason to combine" in conjunction with the technical ability to optimize led to the conclusion that the claimed invention would have been obvious.

The invention in question was a method of treating meat to reduce the incidence of pathogens, by spraying the meat with an antibacterial solution under specified conditions. The parties did not dispute that a single prior art reference had taught all of the elements of the claimed invention, except for the pressure limitation of "at least 50 psi."

FMC had argued at the district court that the claimed invention would have been obvious in view of the first prior art reference mentioned above in view of a second reference that had taught the advantages of spray-treating at pressures of 20 to 150 psi when treating meat with a different antibacterial agent. The district court did not find FMC's argument to be convincing, and denied the motion for judgment as a matter of law that the claim was obvious.

Disagreeing with the district court, the Federal Circuit stated that "there was an apparent reason to combine these known elements—namely to increase contact between the [antibacterial solution] and the bacteria on the meat surface and to use the pressure to wash additional bacteria off the meat surface." *Id.* at 1350. The Federal Circuit explained that because the second reference had taught "using high pressure to improve the effectiveness of an antimicrobial solution when sprayed onto meat, and because an ordinarily skilled artisan would have recognized the reasons for applying [the claimed antibacterial solution] using high pressure and would have known how to do so, Ecolab's claims combining high pressure with other limitations disclosed in FMC's patent are invalid as obvious." *Id.*

When considering the question of obviousness, Office personnel should keep in mind the capabilities of a person of ordinary skill. In *Ecolab,* the Federal Circuit stated:

> Ecolab's expert admitted that one skilled in the art would know how to adjust application parameters to determine the optimum parameters for a particular solution. The question then is whether it would have been obvious to combine the high pressure parameter disclosed in the Bender patent with the PAA methods disclosed in FMC's '676 patent. The answer is yes.

Id. If optimization of the application parameters had not been within the level of ordinary skill in the art, the outcome of the *Ecolab* case may well have been different.

Example 4.5. Wyers v. *Master Lock Co.*, No. 2009–1412, —F.3d—, 2010 WL 2901839 (Fed. Cir. July 22, 2010). *Teaching point:* The scope of analogous art is to be construed broadly and includes references that are reasonably pertinent to the problem that the inventor was trying to solve. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.

In the case of *Wyers* v. *Master Lock Co.*, the Federal Circuit held that the claimed barbell-shaped hitch pin locks used to secure trailers to vehicles were obvious.

The court discussed two different sets of claims in *Wyers,* both drawn to improvements over the prior art hitch pin locks. The first improvement was a removable sleeve that could be placed over the shank of the hitch pin lock so that the same lock could be used with towing apertures of varying sizes. The second improvement was an external flat flange seal adapted to protect the internal lock mechanism from contaminants. Wyers had admitted that each of several prior art references taught every element of the claimed inventions except for the removable sleeve and the external covering. Master Lock had argued that these references, in combination with additional references teaching the missing elements, would have rendered the claims obvious.

The court first addressed the question of whether the additional references relied on by Master Lock were analogous prior art. As to the reference teaching the sleeve improvement, the court concluded that it dealt specifically with using a vehicle to tow a trailer, and was therefore in the same field of endeavor as Wyers' sleeve improvement. The reference teaching the sealing improvement dealt with a padlock rather than a lock for a tow hitch. The court noted that Wyers' specification had characterized the claimed invention as being in the field of locking devices, thus at least suggesting that the sealed padlock reference was in the same field of endeavor. However, the court also observed that even if sealed padlocks were not in the same field of endeavor, they were nevertheless reasonably pertinent to the problem of avoiding contamination of a locking mechanism for tow hitches. The court explained that the Supreme Court's decision in *KSR* "directs [it] to construe the scope of analogous art broadly." *Wyers,* slip. op. at 12. For these reasons, the court found that Master Lock's asserted references were analogous prior art, and therefore relevant to the obviousness inquiry.

The court then turned to the question of whether there would have been adequate motivation to combine the prior art elements as had been urged by Master Lock. The court recalled the *Graham* inquiries, and also emphasized the "expansive and flexible" post-*KSR* approach to obviousness that must not "deny factfinders recourse to common sense." *Wyers,* slip op. at 13 (quoting *KSR,* 550 U.S. at 415 and 421). The court stated:

> *KSR* and our later cases establish that the legal determination of obviousness may include recourse to logic, judgment, and common sense, in lieu of expert testimony * * *.
>
> Thus, in appropriate cases, the ultimate inference as to the existence of a motivation to combine references may boil down to a question of "common sense," appropriate for resolution on summary judgment or JMOL.

Id. at 15 (citing *Perfect Web Techs., Inc.* v. *InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009); *Ball Aerosol,* 555 F.3d at 993).

After reviewing these principles, the court proceeded to explain why adequate motivation to combine had been established in this case. With regard to the sleeve improvement, it pointed out that the need for different sizes of hitch pins was well known in the art, and that this was a known source of inconvenience and expense for users. The court also mentioned the marketplace aspect of the issue, noting that space on store shelves was at a premium, and that removable sleeves addressed this economic concern. As to the sealing improvement, the court pointed out that both internal and external seals were well-known means to protect locks from contaminants. The court concluded that the constituent elements were being employed in accordance with their recognized functions, and would have predictably retained their respective functions when combined as suggested by Master Lock. The court cited *In re O'Farrell,* 853 F.2d 894, 904 (Fed. Cir. 1988) for the proposition that a reasonable expectation of success is a requirement for a proper determination of obviousness.

Office personnel should note that although the Federal Circuit invoked the idea of common sense in support of a conclusion of obviousness, it did not end its explanation there. Rather, the

court explained why a person of ordinary skill in the art at the time of the invention, in view of the facts relevant to the case, would have found the claimed inventions to have been obvious. As stated in the MPEP:

> The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

MPEP § 2141 III. Office personnel should continue to provide a reasoned explanation for every obviousness rejection.

Example 4.6. DePuy Spine, Inc. v. *Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009). *Teaching point:* Predictability as discussed in *KSR* encompasses the expectation that prior art elements are capable of being combined, as well as the expectation that the combination would have worked for its intended purpose. An inference that a claimed combination would not have been obvious is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.

The claim in *DePuy Spine* was directed to a polyaxial pedicle screw used in spinal surgeries that included a compression member for pressing a screw head against a receiver member. A prior art reference (Puno) disclosed all of the elements of the claim except for the compression member. Instead, the screw head in Puno was separated from the receiver member to achieve a shock absorber effect, allowing some motion between receiver member and the vertebrae. The missing compression member was readily found in another prior art reference (Anderson), which disclosed an external fracture immobilization splint for immobilizing long bones with a swivel clamp capable of polyaxial movement until rigidly secured by a compression member. It was asserted during trial that a person of ordinary skill would have recognized that the addition of Anderson's compression member to Puno's device would have achieved a rigidly locked polyaxial pedicle screw covered by the claim.

In conducting its analysis, the Federal Circuit noted that the "predictable result" discussed in *KSR* refers not only to the expectation that prior art elements are capable of being physically combined, but also that the combination would have worked for its intended purpose. In this case, it was successfully argued that Puno "teaches away" from a rigid screw because Puno warned that rigidity increases the likelihood that the screw will fail within the human body, rendering the device inoperative for its intended purpose. In fact, the reference did not merely express a general preference for pedicle screws having a "shock absorber" effect, but rather expressed concern for failure and stated that the shock absorber feature "decrease[s] the chance of failure of the screw of the bone-screw interface" because "it prevent[s] direct transfer of load from the rod to the bone-screw interface." Thus, the alleged reason to combine the prior art elements of Puno and Anderson—increasing the rigidity of the screw—ran contrary to the prior art that taught that increasing rigidity would result in a greater likelihood of failure. In view of this teaching and the backdrop of collective teachings of the prior art, the Federal Circuit determined that Puno teaches away from the proposed combination such that a person of ordinary skill would have been deterred from combining the references as proposed. Secondary considerations evaluated by the Federal Circuit relating to failure by others and copying also supported the view that the combination would not have been obvious at the time of the invention.

B. *Substituting One Known Element for Another.* As explained in the *2007 KSR Guidelines*, the substitution rationale applies when the claimed invention can be viewed as resulting from substituting a known element for an element of a prior art invention. The rationale applies when one of ordinary skill in the art would have been technologically capable of making the substitution, and the result obtained would have been predictable. *See* MPEP § 2143(B).

Example 4.7. In re ICON Health & Fitness, Inc., 496 F.3d 1374 (Fed. Cir. 2007). *Teaching point:* When determining whether a reference in a different field of endeavor may be used to support a case of obviousness (*i.e.*, is analogous), it is necessary to consider the problem to be solved.

The claimed invention in *ICON* was directed to a treadmill with a folding tread base that swivels into an upright storage position, including a gas spring connected between the tread base and the upright structure to assist in stably retaining the tread base in the storage position. On reexamination, the examiner rejected the claims as obvious based on a combination of references including an advertisement (Damark) for a folding treadmill demonstrating all of the claim elements other than the gas spring, and a patent (Teague) with a gas spring. Teague was directed to a bed that folds into a cabinet using a novel dual-action spring that reverses force as the mechanism passes a neutral position, rather than a single-action spring that would provide a force pushing the bed closed at all times. The dual-action spring reduced the force required to open the bed from the closed position, while reducing the force required to lift the bed from the open position.

The Federal Circuit addressed the propriety of making the combination since Teague comes from a different field than the application. Teague was found to be reasonably pertinent to the problem addressed in the application because the folding mechanism did not require any particular focus on treadmills, but rather generally addressed problems of supporting the weight of such a mechanism and providing a stable resting position.

Other evidence was considered concerning whether one skilled in the art would have been led to combine the teachings of Damark and Teague. Appellant argued that Teague teaches away from the invention because it directs one skilled in the art not to use single-action springs and does not satisfy the claim limitations as the dual-action springs would render the invention inoperable. The Federal Circuit considered the arguments and found that while Teague at most teaches away from using single-action springs to decrease the opening force, it actually instructed that single-action springs provide the result desired by the inventors, which was to increase the opening force provided by gravity. As to inoperability, the claims were not limited to single-action springs and were so broad as to encompass anything that assists in stably retaining the tread base, which is the function that Teague accomplished. Additionally, the fact that the counterweight mechanism from Teague used a large spring, which appellant argued would overpower the treadmill mechanism, ignores the modifications that one skilled in the art would make to a device borrowed from the prior art. One skilled in the art would size the components from Teague appropriately for the application.

ICON is another useful example for understanding the scope of analogous art. The art applied concerned retaining mechanisms for folding beds, not treadmills. When determining whether a

reference may properly be applied to an invention in a different field of endeavor, it is necessary to consider the problem to be solved. It is certainly possible that a reference may be drawn in such a way that its usefulness as a teaching is narrowly restricted. However, in *ICON,* the "treadmill" concept was too narrow a lens through which to view the art in light of the prior art teachings concerning the problem to be solved. The Teague reference was analogous art because "Teague and the current application both address the need to stably retain a folding mechanism," *id.* at 1378, and because "nothing about ICON's folding mechanism requires any particular focus on treadmills," *id.* at 1380.

ICON is also informative as to the relationship between the problem to be solved and existence of a reason to combine. "Indeed, while perhaps not dispositive of the issue, the finding that Teague, by addressing a similar problem, provides analogous art to ICON's application goes a long way towards demonstrating a reason to combine the two references. Because ICON's broad claims read on embodiments addressing that problem as described by Teague, the prior art here indicates a reason to incorporate its teachings." *Id.* at 1380–81.

The Federal Circuit's discussion in *ICON* also makes clear that if the reference does not teach that a combination is undesirable, then it cannot be said to teach away. An assessment of whether a combination would render the device inoperable must not "ignore the modifications that one skilled in the art would make to a device borrowed from the prior art." *Id.* at 1382.

Example 4.8. Agrizap, Inc. v. *Woodstream Corp.,* 520 F.3d 1337 (Fed. Cir. 2008). *Teaching point:* Analogous art is not limited to references in the field of endeavor of the invention, but also includes references that would have been recognized by those of ordinary skill in the art as useful for applicant's purpose.

Agrizap involved a stationary pest control device for electrocution of pests such as rats and gophers, in which the device is set in an area where the pest is likely to encounter it. The only difference between the claimed device and the prior art stationary pest control device was that the claimed device employed a resistive electrical switch, while the prior art device used a mechanical pressure switch. A resistive electrical switch was taught in two prior art patents, in the contexts of a hand-held pest control device and a cattle prod.

In determining that the claimed invention was obvious, the Federal Circuit noted that "[t]he asserted claims simply substitute a resistive electrical switch for the mechanical pressure switch" employed in the prior art device. *Id.* at 1344. In this case, the prior art concerning the hand-held devices revealed that the function of the substituted resistive electrical switch was well known and predictable, and that it could be used in a pest control device. According to the Federal Circuit, the references that taught the hand-held devices showed that "the use of an animal body as a resistive switch to complete a circuit for the generation of an electric charge was already well known in the prior art." *Id.* Finally, the Federal Circuit noted that the problem solved by using the resistive electrical switch in the prior art hand-held devices—malfunction of mechanical switches due to dirt and dampness—also pertained to the prior art stationary pest control device.

The Federal Circuit recognized *Agrizap* as "a textbook case of when the asserted claims involve a combination of familiar elements according to known methods that does no more than yield predictable results." *Id. Agrizap* exemplifies a strong case of obviousness based on simple substitution that was not overcome by the objective evidence of nonobviousness offered. It also demonstrates that analogous art is not limited to the field of applicant's endeavor, in that one of the references that used an animal body as a resistive switch to complete a circuit for the generation of an electric charge was not in the field of pest control.

Example 4.9. Muniauction, Inc. v. *Thomson Corp.,* 532 F.3d 1318 (Fed. Cir. 2008). *Teaching point:* Because Internet and Web browser technologies had become commonplace for communicating and displaying information, it would have been obvious to adapt existing processes to incorporate them for those functions.

The invention at issue in *Muniauction* was a method for auctioning municipal bonds over the Internet. A municipality could offer a package of bond instruments of varying principal amounts and maturity dates, and an interested buyer would then submit a bid comprising a price and interest rate for each maturity date. It was also possible for the interested buyer to bid on a portion of the offering. The claimed invention considered all of the noted parameters to determine the best bid. It operated on conventional Web browsers and allowed participants to monitor the course of the auction.

The only difference between the prior art bidding system and the claimed invention was the use of a conventional Web browser. At trial, the district court had determined that Muniauction's claims were not obvious. Thomson argued that the claimed invention amounted to incorporating a Web browser into a prior art auction system, and was therefore obvious in light of *KSR.* Muniauction rebutted the argument by offering evidence of skepticism by experts, copying, praise, and commercial success. Although the district court found the evidence to be persuasive of nonobviousness, the Federal Circuit disagreed. It noted that a nexus between the claimed invention and the proffered evidence was lacking because the evidence was not coextensive with the claims at issue. For this reason, the Federal Circuit determined that Muniauction's evidence of secondary considerations was not entitled to substantial weight.

The Federal Circuit analogized this case to *Leapfrog Enterprises, Inc.* v. *Fisher-Price, Inc.,* 485 F.3d 1157 (Fed. Cir. 2007), cited in the *2007 KSR Guidelines.* The *Leapfrog* case involved a determination of obviousness based on application of modern electronics to a prior art mechanical children's learning device. In *Leapfrog,* the court had noted that market pressures would have prompted a person of ordinary skill to use modern electronics in the prior art device. Similarly in *Muniauction,* market pressures would have prompted a person of ordinary skill to use a conventional Web browser in a method of auctioning municipal bonds.

Example 4.10. *Aventis Pharma Deutschland* v. *Lupin Ltd.,* 499 F.3d 1293 (Fed. Cir. 2007). *Teaching point:* A chemical compound would have been obvious over a mixture containing that compound as well as other compounds where it was known or the skilled artisan had reason to believe that some desirable property of the mixture was derived in whole or in part from the claimed compound, and separating the claimed compound from the mixture was routine in the art.

In *Aventis,* the claims were drawn to the 5(S) stereoisomer of the blood pressure drug ramipril in stereochemically pure form, and to compositions and methods requiring 5(S) ramipril. The 5(S) stereoisomer is one in which all five stereocenters in the ramipril molecule are in the S rather than the R configuration. A mixture of various stereoisomers including 5(S) ramipril had been taught by the prior art. The question before the court was whether the purified single stereoisomer

would have been obvious over the known mixture of stereoisomers.

The record showed that the presence of multiple S stereocenters in drugs similar to ramipril was known to be associated with enhanced therapeutic efficacy. For example, when all of the stereocenters were in the S form in the related drug enalapril (SSS enalapril) as compared with only two stereocenters in the S form (SSR enalapril), the therapeutic potency was 700 times as great. There was also evidence to indicate that conventional methods could be used to separate the various stereoisomers of ramipril.

The district court saw the issue as a close case, because, in its view, there was no clear motivation in the prior art to isolate 5(S) ramipril. However, the Federal Circuit disagreed, and found that the claims would have been obvious. The Federal Circuit cautioned that requiring such a clearly stated motivation in the prior art to isolate 5(S) ramipril ran counter to the Supreme Court's decision in *KSR*. The court stated:

> Requiring an explicit teaching to purify the 5(S) stereoisomer from a mixture in which it is the active ingredient is precisely the sort of rigid application of the TSM test that was criticized in *KSR*.

Id. at 1301. The *Aventis* court also relied on the settled principle that in chemical cases, structural similarity can provide the necessary reason to modify prior art teachings. The Federal Circuit also addressed the kind of teaching that would be sufficient in the absence of an explicitly stated prior art-based motivation, explaining that an expectation of similar properties in light of the prior art can be sufficient, even without an explicit teaching that the compound will have a particular utility.

In the chemical arts, the cases involving so-called "lead compounds" form an important subgroup of the obviousness cases that are based on substitution. The Federal Circuit has had a number of opportunities since the *KSR* decision to discuss the circumstances under which it would have been obvious to modify a known compound to arrive at a claimed compound. The following cases explore the selection of a lead compound, the need to provide a reason for any proposed modification, and the predictability of the result.

Example 4.11. Eisai Co. Ltd. v. *Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008). *Teaching point:* A claimed compound would not have been obvious where there was no reason to modify the closest prior art lead compound to obtain the claimed compound and the prior art taught that modifying the lead compound would destroy its advantageous property. Any known compound may serve as a lead compound when there is some reason for starting with that lead compound and modifying it to obtain the claimed compound.

Eisai concerns the pharmaceutical compound rabeprazole. Rabeprazole is a proton pump inhibitor for treating stomach ulcers and related disorders. The Federal Circuit affirmed the district court's summary judgment of nonobviousness, stating that no reason had been advanced to modify the prior art compound in a way that would destroy an advantageous property.

Co-defendant Teva based its obviousness argument on the structural similarity between rabeprazole and lansoprazole. The compounds were recognized as sharing a common core, and the Federal Circuit characterized lansoprazole as a "lead compound." The prior art compound lansoprazole was useful for the same indications as rabeprazole, and differed from rabeprazole only in that lansoprazole has a trifluoroethoxy substituent at the 4-position of the pyridine ring, while rabeprazole has a methoxypropoxy substituent. The trifluoro substituent of lansoprazole was known to be a beneficial feature because it conferred lipophilicity to the compound. The ability of a person of ordinary skill to carry out the modification to introduce the methoxypropoxy substituent, and the predictability of the result were not addressed.

Despite the significant similarity between the structures, the Federal Circuit did not find any sufficient reason to modify the lead compound. According to the Federal Circuit:

> Obviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (*i.e.* a lead compound) in a particular way to achieve the claimed compound. * * * In keeping with the flexible nature of the obviousness inquiry, *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727, 1739, 167 L.Ed.2d 705 (2007), the requisite motivation can come from any number of sources and need not necessarily be explicit in the art. See *Aventis Pharma Deutschland GmbH* v. *Lupin, Ltd.*, 499 F.3d 1293, 1301 (Fed. Cir. 2007). Rather "it is sufficient to show that the claimed and prior art compounds possess a 'sufficiently close relationship * * * to create an expectation,' in light of the totality of the prior art, that the new compound will have 'similar properties' to the old." *Id.* (quoting *Dillon*, 919 F.2d at 692).

Eisai, 533 F.3d at 1357. The prior art taught that introducing a fluorinated substituent was known to increase lipophilicity, so a skilled artisan would have expected that replacing the trifluoroethoxy substituent with a methoxypropoxy substituent would have reduced the lipophilicity of the compound. Thus, the prior art created the expectation that rabeprazole would be less useful than lansoprazole as a drug for treating stomach ulcers and related disorders because the proposed modification would have destroyed an advantageous property of the prior art compound. The compound was not obvious as argued by Teva because, upon consideration of all of the facts of the case, a person of ordinary skill in the art at the time of the invention would not have had a reason to modify lansoprazole so as to form rabeprazole.

Office personnel are cautioned that the term "lead compound" in a particular opinion can have a contextual meaning that may vary from the way a pharmaceutical chemist might use the term. In the field of pharmaceutical chemistry, the term "lead compound" has been defined variously as "a chemical compound that has pharmacological or biological activity and whose chemical structure is used as a starting point for chemical modifications in order to improve potency, selectivity, or pharmacokinetic parameters;" "[a] compound that exhibits pharmacological properties which suggest its development;" and "a potential drug being tested for safety and efficacy." *See, e.g., http://en.wikipedia.org/wiki/Lead_compound,* accessed January 13, 2010; *http://www.combichemistry.com/glossary_k.html,* accessed January 13, 2010; and *http://www.buildingbiotechnology.com/glossary4.php,* accessed January 13, 2010.

The Federal Circuit in *Eisai* makes it clear that from the perspective of the law of obviousness, any known compound might possibly serve as a lead compound: "Obviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (*i.e.* a lead compound) in a particular way to achieve the claimed compound." *Eisai*, 533 F.3d at 1357. Thus, Office personnel should recognize that a proper obviousness rejection of a claimed compound that is useful as a drug might be made beginning with an inactive compound, if, for example, the reasons for modifying a prior art compound to arrive at the claimed compound have nothing to do with pharmaceutical activity. The inactive compound would not be considered to be a lead

compound by pharmaceutical chemists, but could potentially be used as such when considering obviousness. Office personnel might also base an obviousness rejection on a known compound that pharmaceutical chemists would not select as a lead compound due to expense, handling issues, or other business considerations. However, there must be some reason for starting with that lead compound other than the mere fact that the "lead compound" merely exists. *See Altana Pharma AG* v. *Teva Pharmaceuticals USA, Inc.*, 566 F.3d 999, 1007 (Fed. Cir. 2009) (holding that there must be some reason "to select and modify a known compound"); *Ortho-McNeil Pharmaceutical, Inc.* v. *Mylan Labs, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

Example 4.12. Procter & Gamble Co. v. *Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989 (Fed. Cir. 2009). *Teaching point:* It is not necessary to select a single compound as a "lead compound" in order to support an obviousness rejection. However, where there was reason to select and modify the lead compound to obtain the claimed compound, but no reasonable expectation of success, the claimed compound would not have been obvious.

A chemical compound was also found to be nonobvious in *Procter & Gamble.* The compound at issue was risedronate—the active ingredient of Procter & Gamble's osteoporosis drug Actonel®. Risedronate is an example of a bisphosphonate, which is a class of compounds known to inhibit bone resorption.

When Procter & Gamble sued Teva for infringement, Teva defended by arguing invalidity for obviousness over one of Procter & Gamble's earlier patents. The prior art patent did not teach risedronate, but instead taught thirty-six other similar compounds including 2-pyr EHDP that were potentially useful with regard to osteoporosis. Teva argued obviousness on the basis of structural similarity to 2-pyr EHDP, which is a positional isomer of risedronate.

The district court found no reason to select 2-pyr EHDP as a lead compound in light of the unpredictable nature of the art, and no reason to modify it so as to obtain risedronate. In addition, there were unexpected results as to potency and toxicity. Therefore the district court found that Teva had not made a *prima facie* case, and even if it had, it was rebutted by evidence of unexpected results.

The Federal Circuit affirmed the district court's decision. The Federal Circuit did not deem it necessary in this case to consider the question of whether 2-pyr EHDP had been appropriately selected as a lead compound. Rather, the Federal Circuit stated that if 2-pyr EHDP is presumed to be an appropriate lead compound, there must be both a reason to modify it so as to make risedronate, and a reasonable expectation of success. Here there was no evidence that the necessary modifications would have been routine, so there would have been no reasonable expectation of success.

Procter & Gamble is also informative in its discussion of the treatment of secondary considerations of non-obviousness. Although the court found that no *prima facie* case of obviousness had been presented, it proceeded to analyze Procter & Gamble's proffered evidence countering the alleged *prima facie* case in some detail, thus shedding light on the proper treatment of such evidence.

The Federal Circuit noted in dicta that even if a *prima facie* case of obviousness had been established, sufficient evidence of unexpected results was introduced to rebut such a showing. At trial, the witnesses consistently testified that the properties of risedronate were not expected, offering evidence that researchers did not predict either the potency or the low dose at which the compound was effective, and that the superior properties were unexpected and could not be predicted. Tests comparing risedronate to a compound in the prior art reference showed that risedronate outperformed the other compound by a substantial margin, could be administered in a greater amount without an observable toxic effect, and was not lethal at the same levels as the other compound. The weight of the evidence and the credibility of the witnesses were sufficient to show unexpected results that would have rebutted an obviousness determination. Thus, nonobviousness can be shown when a claimed invention is shown to have unexpectedly superior properties when compared to the prior art.

The court then addressed the evidence of commercial success of risedronate and the evidence that risedronate met a long-felt need. The court pointed out that little weight was to be afforded to the commercial success because the competing product was also assigned to Procter & Gamble. However, the Federal Circuit affirmed the district court's conclusion that risedronate met a long-felt, unsatisfied need. The court rejected Teva's contention that because the competing drug was available before Actonel®, there was no unmet need that the invention satisfied. The court emphasized that whether there was a long-felt unsatisfied need is to be evaluated based on the circumstances as of the filing date of the challenged invention—not as of the date that the invention is brought to market.

It should be noted that the lead compound cases do not stand for the proposition that identification of a single lead compound is necessary in every obviousness rejection of a chemical compound. For example, one might envision a suggestion in the prior art to formulate a compound having certain structurally defined moieties, or moieties with certain properties. If a person of ordinary skill would have known how to synthesize such a compound, and the structural and/or functional result could reasonably have been predicted, then a *prima facie* case of obviousness of the claimed chemical compound might exist even without identification of a particular lead compound. As a second example, it could be possible to view a claimed compound as consisting of two known compounds attached via a chemical linker. The claimed compound might properly be found to have been obvious if there would have been a reason to link the two, if one of ordinary skill would have known how to do so, and if the resulting compound would have been the predictable result of the linkage procedure. Thus, Office personnel should recognize that in certain situations, it may be proper to reject a claimed chemical compound as obvious even without identifying a single lead compound.

Example 4.13. Altana Pharma AG v. *Teva Pharmaceuticals USA, Inc.*, 566 F.3d 999 (Fed. Cir. 2009). *Teaching point:* Obviousness of a chemical compound in view of its structural similarity to a prior art compound may be shown by identifying some line of reasoning that would have led one of ordinary skill in the art to select and modify a prior art lead compound in a particular way to produce the claimed compound. It is not necessary for the reasoning to be explicitly found in the prior art of record, nor is it necessary for the prior art to point to only a single lead compound.

Although the decision reached by the Federal Circuit in *Altana* involved a motion for preliminary injunction and did not include a final determination of obviousness, the case is nevertheless instructive as to the issue of selecting a lead compound.

The technology involved in Altana was the compound pantoprazole, which is the active ingredient in Altana's antiulcer drug Protonix®. Pantoprazole belongs to a class of compounds known

as proton pump inhibitors that are used to treat gastric acid disorders in the stomach.

Altana accused Teva of infringement. The district court denied Altana's motion for preliminary injunction for failure to establish a likelihood of success on the merits, determining that Teva had demonstrated a substantial question of invalidity for obviousness in light of one of Altana's prior patents. Altana's patent discussed a compound referred to as compound 12, which was one of eighteen compounds disclosed. The claimed compound pantoprazole was structurally similar to compound 12. The district court found that one of ordinary skill in the art would have selected compound 12 as a lead compound for modification, and the Federal Circuit affirmed.

Obviousness of a chemical compound in view of its structural similarity to a prior art compound may be shown by identifying some line of reasoning that would have led one of ordinary skill in the art to select and modify the prior art compound in a particular way to produce the claimed compound. The necessary line of reasoning can be drawn from any number of sources and need not necessarily be explicitly found in the prior art of record. The Federal Circuit determined that ample evidence supported the district court's finding that compound 12 was a natural choice for further development. For example, Altana's prior art patent claimed that its compounds, including compound 12, were improvements over the prior art; compound 12 was disclosed as one of the more potent of the eighteen compounds disclosed; the patent examiner had considered the compounds of Altana's prior art patent to be relevant during the prosecution of the patent in suit; and experts had opined that one of ordinary skill in the art would have selected the eighteen compounds to pursue further investigation into their potential as proton pump inhibitors.

In response to Altana's argument that the prior art must point to only a single lead compound for further development, the Federal Circuit stated that a "restrictive view of the lead compound test would present a rigid test similar to the teaching-suggestion-motivation test that the Supreme Court explicitly rejected in *KSR* * * *. The district court in this case employed a flexible approach—one that was admittedly preliminary—and found that the defendants had raised a substantial question that one of skill in the art would have used the more potent compounds of [Altana's prior art] patent, including compound 12, as a starting point from which to pursue further development efforts. That finding was not clearly erroneous." *Id.* at 1008.

C. *The "Obvious to Try" Rationale.* The question of whether a claimed invention can be shown to be obvious based on an "obvious to try" line of reasoning has been explored extensively by the Federal Circuit in several cases since the *KSR* decision. The *2007 KSR Guidelines* explain, in view of the Supreme Court's instruction, that this rationale is only appropriate when there is a recognized problem or need in the art; there are a finite number of identified, predictable solutions to the recognized need or problem; and one of ordinary skill in the art could have pursued these known potential solutions with a reasonable expectation of success. The case law in this area is developing quickly in the chemical arts, although the rationale has been applied in other art areas as well.

Some commentators on the *KSR* decision have expressed a concern that because inventive activities are always carried out in the context of what has come before and not in a vacuum, few inventions will survive scrutiny under an obvious to try standard. The cases decided since *KSR* have proved this fear to have been unfounded. Courts appear to be applying the *KSR* requirement for "a finite number of identified predictable solutions" in a manner that places particular emphasis on predictability and the reasonable expectations of those of ordinary skill in the art.

In a recent Federal Circuit decision, the court pointed out the challenging nature of the task faced by the courts—and likewise by Office personnel—when considering the viability of an obvious to try argument: "The evaluation of the choices made by a skilled scientist, when such choices lead to the desired result, is a challenge to judicial understanding of how technical advance is achieved in the particular field of science or technology." *Abbott Labs.* v. *Sandoz, Inc.*, 544 F.3d 1341, 1352 (Fed. Cir. 2008). The Federal Circuit cautioned that an obviousness inquiry based on an obvious to try rationale must always be undertaken in the context of the subject matter in question, "including the characteristics of the science or technology, its state of advance, the nature of the known choices, the specificity or generality of the prior art, and the predictability of results in the area of interest." *Id.*

Example 4.14. In re Kubin, 561 F.3d 1351 (Fed. Cir. 2009). *Teaching point:* A claimed polynucleotide would have been obvious over the known protein that it encodes where the skilled artisan would have had a reasonable expectation of success in deriving the claimed polynucleotide using standard biochemical techniques, and the skilled artisan would have had a reason to try to isolate the claimed polynucleotide. *KSR* applies to all technologies, rather than just the "predictable" arts.

The Federal Circuit's decision in *In re Kubin* was an affirmance of the Board's decision in *Ex parte Kubin*, 83 USPQ2d 1410 (Bd. Pat. App. & Interf. 2007), and the Board in turn had affirmed the examiner's determination that the claims in question would have been obvious over the prior art applied. A discussion of *Ex parte Kubin* was included in the *2007 KSR Guidelines. See 2007 KSR Guidelines*, 72 FR at 57532. The claimed invention in *Kubin* was an isolated nucleic acid molecule. The claim stated that the nucleic acid encoded a particular polypeptide. The encoded polypeptide was identified in the claim by its partially specified sequence, and by its ability to bind to a specified protein. A prior art patent to Valiante taught the polypeptide encoded by the claimed nucleic acid, but did not disclose either the sequence of the polypeptide, or the claimed isolated nucleic acid molecule. However, Valiante did disclose that by employing conventional methods, such as those disclosed by a prior art laboratory manual by Sambrook, the sequence of the polypeptide could be determined, and the nucleic acid molecule could be isolated. In view of Valiante's disclosure of the polypeptide, and of routine prior art methods for sequencing the polypeptide and isolating the nucleic acid molecule, the Board found that a person of ordinary skill in the art would have had a reasonable expectation that a nucleic acid molecule within the claimed scope could have been successfully obtained.

Relying on *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), Appellant argued that it was improper for the Office to use the polypeptide of the Valiante patent together with the methods described in Sambrook to reject a claim drawn to a specific nucleic acid molecule without providing a reference showing or suggesting a structurally similar nucleic acid molecule. Citing *KSR*, the Board stated that "when there is motivation to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." The Board noted that

the problem facing those in the art was to isolate a specific nucleic acid, and there were a limited number of methods available to do so. The Board concluded that the skilled artisan would have had reason to try these methods with the reasonable expectation that at least one would be successful. Thus, isolating the specific nucleic acid molecule claimed was "the product not of innovation but of ordinary skill and common sense." The Board's reasoning was substantially adopted by the Federal Circuit. However, it is important to note that in the *Kubin* decision, the Federal Circuit held that "the Supreme Court in *KSR* unambiguously discredited" the Federal Circuit's decision in *Deuel,* insofar as it "implies the obviousness inquiry cannot consider that the combination of the claim's constituent elements was 'obvious to try.'" *Kubin,* 561 F.3d at 1358. Instead, *Kubin* stated that *KSR* "resurrects" the Federal Circuit's own wisdom in *O'Farrell,* in which "to differentiate between proper and improper applications of 'obvious to try,'" the Federal Circuit "outlined two classes of situations where 'obvious to try' is erroneously equated with obviousness under § 103." *Kubin,* 561 F.3d at 1359. These two classes of situations are: (1) When what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful; and (2) when what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. *Id.* (citing *O'Farrell,* 853 F.2d at 903).

Example 4.15. Takeda Chemical Industries, Ltd. v. *Alphapharm Pty., Ltd.,* 492 F.3d 1350 (Fed. Cir. 2007). *Teaching point:* A claimed compound would not have been obvious where it was not obvious to try to obtain it from a broad range of compounds, any one of which could have been selected as the lead compound for further investigation, and the prior art taught away from using a particular lead compound, and there was no predictability or reasonable expectation of success in making the particular modifications necessary to transform the lead compound into the claimed compound.

Takeda is an example of a chemical case in which the Federal Circuit found that the claim was not obvious. The claimed compound was pioglitazone, a member of a class of drugs known as thiazolidinediones (TZDs) marketed by Takeda as a treatment for Type 2 diabetes. The *Takeda* case brings together the concept of a "lead compound" and the obvious-to-try argument.

Alphapharm had filed an Abbreviated New Drug Application with the Food and Drug Administration, which was a technical act of infringement of Takeda's patent. When Takeda brought suit, Alphapharm's defense was that Takeda's patent was invalid due to obviousness. Alphapharm argued that a two-step modification—involving homologation and ring-walking—of a known compound identified as "compound b" would have produced pioglitazone, and that it was therefore obvious.

The district court found that there would have been no reason to select compound b as a lead compound. There were a large number of similar prior art TZD compounds; fifty-four were specifically identified in Takeda's prior patent, and the district court observed that "hundreds of millions" were more generally disclosed. Although the parties agreed that compound b represented the closest prior art, one reference had taught certain disadvantageous properties associated with compound b, which according to the district court would have taught the skilled artisan not to select that compound as a lead compound. The district court found no *prima facie* case of obviousness, and stated that even if a *prima facie* case had been established, it would have been overcome in this case in view of the unexpected lack of toxicity of pioglitazone.

The Federal Circuit affirmed the decision of the district court, citing the need for a reason to modify a prior art compound. The Federal Circuit quoted *KSR,* stating:

> The *KSR* Court recognized that "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR,* 127 S.Ct. at 1732. In such circumstances, "the fact that a combination was obvious to try might show that it was obvious under § 103." *Id.* That is not the case here. Rather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation. Significantly, the closest prior art compound (compound b, the 6-methyl) exhibited negative properties that would have directed one of ordinary skill in the art away from that compound. Thus, this case fails to present the type of situation contemplated by the Court when it stated that an invention may be deemed obvious if it was "obvious to try." The evidence showed that it was not obvious to try.
>
> *Takeda,* 492 F.3d at 1359.

Accordingly, Office personnel should recognize that the obvious to try rationale does not apply when the appropriate factual findings cannot be made. In *Takeda,* there was a recognized need for treatment of diabetes. However, there was no finite number of identified, predictable solutions to the recognized need, and no reasonable expectation of success. There were numerous known TZD compounds, and although one clearly represented the closest prior art, its known disadvantages rendered it unsuitable as a starting point for further research, and taught the skilled artisan away from its use. Furthermore, even if there had been reason to select compound b, there had been no predictability or reasonable expectation of success associated with the particular modifications necessary to transform compound b into the claimed compound pioglitazone. Thus, an obviousness rejection based on an obvious to try rationale was not appropriate in this situation.

Example 4.16. Ortho-McNeil Pharmaceutical, Inc. v. *Mylan Labs, Inc.,* 520 F.3d 1358 (Fed. Cir. 2008). *Teaching point:* Where the claimed anti-convulsant drug had been discovered somewhat serendipitously in the course of research aimed at finding a new anti-diabetic drug, it would not have been obvious to try to obtain a claimed compound where the prior art did not present a finite and easily traversed number of potential starting compounds, and there was no apparent reason for selecting a particular starting compound from among a number of unpredictable alternatives.

The *Ortho-McNeil* case provides another example in which a chemical compound was determined not to be obvious. The claimed subject matter was topiramate, which is used as an anti-convulsant. As in *DePuy Spine,* whether the combination would predictably be effective for its intended purpose is part of the obviousness analysis.

In the course of working toward a new anti-diabetic drug, Ortho-McNeil's scientist had unexpectedly discovered that a reaction intermediate had anti-convulsant properties. Mylan's defense of invalidity due to obviousness rested on an obvious to try argument. However, Mylan did not explain why it would have been obvious to begin with an anti-diabetic drug precursor, especially the specific one that led to

topiramate, if one had been seeking an anti-convulsant drug. The district court ruled on summary judgment that Ortho-McNeil's patent was not invalid for obviousness.

The Federal Circuit affirmed. The Federal Circuit pointed out that there was no apparent reason why a person of ordinary skill would have chosen the particular starting compound or the particular synthetic pathway that led to topiramate as an intermediate. Furthermore, there would have been no reason to test that intermediate for anticonvulsant properties if treating diabetes had been the goal. The Federal Circuit recognized an element of serendipity in this case, which runs counter to the requirement for predictability. Summarizing their conclusion with regard to Mylan's obvious to try argument, the Federal Circuit stated:

> [T]his invention, contrary to Mylan's characterization, does not present a finite (and small in the context of the art) number of options easily traversed to show obviousness * * *. *KSR* posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness* * *. [T]his clearly is not the easily traversed, small and finite number of alternatives that *KSR* suggested might support an inference of obviousness.

Id. at 1364. Thus, *Ortho-McNeil* helps to clarify the Supreme Court's requirement in *KSR* for "a finite number" of predictable solutions when an obvious to try rationale is applied: Under the Federal Circuit's case law "finite" means "small or easily traversed" in the context of the art in question. As taught in *Abbott,* discussed above, it is essential that the inquiry be placed in the context of the subject matter at issue, and each case must be decided on its own facts.

Example 4.17. Bayer Schering Pharma A.G. v. *Barr Labs., Inc.,* 575 F.3d 1341 (Fed. Cir. 2009). *Teaching point:* A claimed compound would have been obvious where it was obvious to try to obtain it from a finite and easily traversed number of options that was narrowed down from a larger set of possibilities by the prior art, and the outcome of obtaining the claimed compound was reasonably predictable.

In *Bayer* the claimed invention was an oral contraceptive containing micronized drospirenone marketed as Yasmin®.

The prior art compound drospirenone was known to be a poorly water-soluble, acid-sensitive compound with contraceptive effects. It was also known in the art that micronization improves the solubility of poorly water soluble drugs.

Based on the known acid sensitivity, Bayer had studied how effectively an enteric-coated drospirenone tablet delivered a formulation as compared to an intravenous injection of the same formulation to measure the "absolute bioavailability" of the drug. Bayer added an unprotected (normal) drospirenone tablet and compared its bioavailability to that of the enteric-coated formulation and the intravenous delivery. Bayer expected to find that the enteric-coated tablet would produce a lower bioavailability than an intravenous injection, while the normal pill would produce an even lower bioavailability than the enteric-coated tablet. However, they found that despite observations that drospirenone would quickly isomerize in a highly acidic environment (supporting the belief that an enteric coating would be necessary to preserve bioavailability), the normal pill and the enteric-coated pill resulted in the same bioavailability. Following this study, Bayer developed micronized drospirenone in a normal pill, the basis for the disputed patent.

The district court found that a person having ordinary skill in the art would have considered the prior art result that a structurally related compound, spirorenone, though acid-sensitive, would nevertheless absorb *in vivo,* would have suggested the same result for drospirenone. It also found that while another reference taught that drospirenone isomerizes *in vitro* when exposed to acid simulating the human stomach, a person of ordinary skill would have been aware of the study's shortcomings, and would have verified the findings as suggested by a treatise on the science of dosage form design, which would have then showed that no enteric coating was necessary.

The Federal Circuit held that the patent was invalid because the claimed formulation was obvious. The Federal Circuit reasoned that the prior art would have funneled the formulator toward two options. Thus, the formulator would not have been required to try all possibilities in a field unreduced by the prior art. The prior art was not vague in pointing toward a general approach or area of exploration, but rather guided the formulator precisely to the use of either a normal pill or an enteric-coated pill.

It is important for Office personnel to recognize that the mere existence of a large number of options does not in and of itself lead to a conclusion of nonobviousness. Where the prior art teachings lead one of ordinary skill in the art to a narrower set of options, then that reduced set is the appropriate one to consider when determining obviousness using an obvious to try rationale.

Example 4.18. Sanofi-Synthelabo v. *Apotex, Inc.,* 550 F.3d 1075 (Fed. Cir. 2008). *Teaching point:* A claimed isolated stereoisomer would not have been obvious where the claimed stereoisomer exhibits unexpectedly strong therapeutic advantages over the prior art racemic mixture without the correspondingly expected toxicity, and the resulting properties of the enantiomers separated from the racemic mixture were unpredictable.

The case of *Sanofi* also sheds light on the obvious to try line of reasoning. The claimed compound was clopidogrel, which is the dextrorotatory isomer of methyl alpha-5(4,5,6,7-tetrahydro(3,2-c)thienopyridyl)(2-chlorophenyl)-acetate. Clopidogrel is an anti-thrombotic compound used to treat or prevent heart attack or stroke. The racemate, or mixture of dextrorotatory and levorotatory (D- and L-) isomers of the compound, was known in the prior art. The two forms had not previously been separated, and although the mixture was known to have anti-thrombotic properties, the extent to which each of the individual isomers contributed to the observed properties of the racemate was not known and was not predictable.

The district court assumed that in the absence of any additional information, the D-isomer would have been *prima facie* obvious over the known racemate. However, in view of the evidence of unpredicted therapeutic advantages of the D-isomer presented in the case, the district court found that any *prima facie* case of obviousness had been overcome. At trial, the experts for both parties testified that persons of ordinary skill in the art could not have predicted the degree to which the isomers would have exhibited different levels of therapeutic activity and toxicity. Both parties' experts also agreed that the isomer with greater therapeutic activity would most likely have had greater toxicity. Sanofi witnesses testified that Sanofi's own researchers had believed that the separation of the isomers was unlikely to have been productive, and experts for both parties agreed that it was difficult to separate isomers at the time of the invention. Nevertheless, when Sanofi ultimately undertook the task of separating the isomers, it found that they had the "rare characteristic of 'absolute stereoselectivity,'" whereby the D-isomer provided all of the favorable therapeutic activity but no significant toxicity, while the L-isomer produced no therapeutic activity but

virtually all of the toxicity. Based on this record, the district court concluded that Apotex had not met its burden of proving by clear and convincing evidence that Sanofi's patent was invalid for obviousness. The Federal Circuit affirmed the district court's conclusion.

Office personnel should recognize that even when only a small number of possible choices exist, the obvious to try line of reasoning is not appropriate when, upon consideration of all of the evidence, the outcome would not have been reasonably predictable and the inventor would not have had a reasonable expectation of success. In *Bayer,* there were art-based reasons to expect that both the normal pill and the enteric-coated pill would be therapeutically suitable, even though not all prior art studies were in complete agreement. Thus, the result obtained was not unexpected. In *Sanofi,* on the other hand, there was strong evidence that persons of ordinary skill in the art, prior to the separation of the isomers, would have had no reason to expect that the D-isomer would have such strong therapeutic advantages as compared with the L-isomer. In other words, the result in *Sanofi* was unexpected.

Example 4.19. Rolls-Royce, PLC v. *United Technologies Corp.*, 603 F.3d 1325 (Fed. Cir. 2010). *Teaching point:* An obvious to try rationale may be proper when the possible options for solving a problem were known and finite. However, if the possible options were not either known or finite, then an obvious to try rationale cannot be used to support a conclusion of obviousness.

In *Rolls-Royce* the Federal Circuit addressed the obvious to try rationale in the context of a fan blade for jet engines. The case had arisen out of an interference proceeding. Finding that the district court had correctly determined that there was no interference-in-fact because Rolls-Royce's claims would not have been obvious in light of United's application, the Federal Circuit affirmed.

The Federal Circuit described the fan blade of the count as follows:

> Each fan blade has three regions—an inner, an intermediate, and an outer region. The area closest to the axis of rotation at the hub is the inner region. The area farthest from the center of the engine and closest to the casing surrounding the engine is the outer region. The intermediate region falls in between. The count defines a fan blade with a swept-forward inner region, a swept-rearward intermediate region, and forward-leaning outer region.

Id. at 1328.

United had argued that it would have been obvious for a person of ordinary skill in the art to try a fan blade design in which the sweep angle in the outer region was reversed as compared with prior art fan blades from rearward to forward sweep, in order to reduce endwall shock. The Federal Circuit disagreed with United's assessment that the claimed fan blade would have been obvious based on an obvious to try rationale. The Federal Circuit pointed out that in a proper obvious to try approach to obviousness, the possible options for solving a problem must have been "known and finite." *Id.* at 1339, citing *Abbott,* 544 F.3d at 1351. In this case, there had been no suggestion in the prior art that would have suggested that changing the sweep angle as Rolls-Royce had done would have addressed the issue of endwall shock. Thus, the Federal Circuit concluded that changing the sweep angle "would not have presented itself as an option at all, let alone an option that would have been obvious to try." *Rolls-Royce,* 603 F.3d at 1339. The decision in *Rolls-Royce* is a reminder to Office personnel that the obvious to try rationale can properly be used to support a conclusion of obviousness only when the claimed solution would have been selected from a finite number of potential solutions known to persons of ordinary skill in the art.

Example 4.20. Perfect Web Technologies, Inc. v. *InfoUSA, Inc.*, 587 F.3d 1324, 1328–29 (Fed. Cir. 2009). *Teaching point:* Where there were a finite number of identified, predictable solutions and there is no evidence of unexpected results, an obvious to try inquiry may properly lead to a legal conclusion of obviousness. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.

The *Perfect Web* case provides an example in which the Federal Circuit held that a claimed method for managing bulk e-mail distribution was obvious on the basis of an obvious to try argument. In *Perfect Web,* the method required selecting the intended recipients, transmitting the e-mails, determining how many of the e-mails had been successfully received, and repeating the first three steps if a pre-determined minimum number of intended recipients had not received the e-mail.

The Federal Circuit affirmed the district court's determination on summary judgment that the claimed invention would have been obvious. Failure to meet a desired quota of e-mail recipients was a recognized problem in the field of e-mail marketing. The prior art had also recognized three potential solutions: Increasing the size of the initial recipient list; resending e-mails to recipients who did not receive them on the first attempt; and selecting a new recipient list and sending e-mails to them. The last option corresponded to the fourth step of the invention as claimed.

The Federal Circuit noted that based on "simple logic," selecting a new list of recipients was more likely to result in the desired outcome than resending to those who had not received the e-mail on the first attempt. There had been no evidence of any unexpected result associated with selecting a new recipient list, and no evidence that the method would not have had a reasonable likelihood of success. Thus, the Federal Circuit concluded that, as required by *KSR,* there were a "finite number of identified, predictable solutions," and that the obvious to try inquiry properly led to the legal conclusion of obviousness.

The Federal Circuit in *Perfect Web* also discussed the role of common sense in the determination of obviousness. The district court had cited *KSR* for the proposition that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton," and found that "the final step [of the claimed invention] is merely the logical result of common sense application of the maxim 'try, try again.'" In affirming the district court, the Federal Circuit undertook an extended discussion of common sense as it has been applied to the obviousness inquiry, both before and since the *KSR* decision.

The Federal Circuit pointed out that application of common sense is not really an innovation in the law of obviousness when it stated, "Common sense has long been recognized to inform the analysis of obviousness **if explained with sufficient reasoning.**" *Perfect Web,* 587 F.3d at 1328 (emphasis added). The Federal Circuit then provided a review of a number of precedential cases that inform the understanding of common sense, including *In re Bozek,* 416 F.2d 1385, 1390 (CCPA 1969) (explaining that a patent examiner may rely on "common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference") and *In re Zurko,* 258 F.3d 1379, 1383, 1385 (Fed. Cir. 2001) (clarifying that a factual foundation is needed in order for an examiner to invoke "good common sense" in a case in which "basic knowledge and common sense was not based on any evidence in the record").

The Federal Circuit implicitly acknowledged in *Perfect Web* that the kind of strict evidence-based teaching, suggestion, or motivation required in *In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002), is not an absolute requirement for an obviousness rejection in light of the teachings of *KSR*. The Federal Circuit explained that "[a]t the time [of the *Lee* decision], we required the PTO to identify record evidence of a teaching, suggestion, or motivation to combine references." However, *Perfect Web* went on to state that even under *Lee*, common sense could properly be applied when analyzing evidence relevant to obviousness. Citing *DyStar Textilfarben GmbH* v. *C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006), and *In re Kahn*, 441 F.3d 977 (Fed. Cir. 2006), two cases decided shortly before the Supreme Court's decision in *KSR*, the Federal Circuit noted that although "a reasoned explanation that avoids conclusory generalizations" is required to use common sense, identification of a "specific hint or suggestion in a particular reference" is not.

5. *Federal Circuit Cases Discussing Consideration of Evidence.* Office personnel should consider all rebuttal evidence that is timely presented by the applicants when reevaluating any obviousness determination. In the case of a claim rendered obvious by a combination of prior art references, applicants may submit evidence or argument to demonstrate that the results of the claimed combination were unexpected.

Another area that has thus far remained consistent with pre-*KSR* precedent is the consideration of rebuttal evidence and secondary considerations in the determination of obviousness. As reflected in the MPEP, such evidence should not be considered simply for its "knockdown" value; rather, all evidence must be reweighed to determine whether the claims are nonobvious.

Once the applicant has presented rebuttal evidence, Office personnel should reconsider any initial obviousness determination in view of the entire record. *See, e.g., In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984); *In re Eli Lilly & Co.*, 90 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). All the rejections of record and proposed rejections and their bases should be reviewed to confirm their continued viability.

MPEP § 2141.

Office personnel should not evaluate rebuttal evidence for its "knockdown" value against the *prima facie* case, *Piasecki*, 745 F.2d at 1473, 223 USPQ at 788, or summarily dismiss it as not compelling or insufficient. If the evidence is deemed insufficient to rebut the *prima facie* case of obviousness, Office personnel should specifically set forth the facts and reasoning that justify this conclusion.

MPEP § 2145. The following cases exemplify the continued application of these principles both at the Federal Circuit and within the Office. Note that these principles were at issue in some of the cases previously discussed, and have been addressed there in a more cursory fashion.

Example 5.1. PharmaStem Therapeutics, Inc. v. *Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007). *Teaching point:* Even though all evidence must be considered in an obviousness analysis, evidence of nonobviousness may be outweighed by contradictory evidence in the record or by what is in the specification. Although a reasonable expectation of success is needed to support a case of obviousness, absolute predictability is not required.

The claims at issue in *PharmaStem* were directed to compositions comprising hematopoietic stem cells from umbilical cord or placental blood, and to methods of using such compositions for treatment of blood and immune system disorders. The composition claims required that the stem cells be present in an amount sufficient to effect hematopoietic reconstitution when administered to a human adult. The trial court had found that PharmaStem's patents were infringed and not invalid on obviousness or other grounds. On appeal, the Federal Circuit reversed the district court, determining that the claims were invalid for obviousness.

The Federal Circuit discussed the evidence presented at trial. It pointed out that the patentee, PharmaStem, had not invented an entirely new procedure or new composition. Rather, PharmaStem's own specification acknowledged that it was already known in the prior art that umbilical cord and placental blood-based compositions contained hematopoietic stem cells, and that hematopoietic stem cells were useful for the purpose of hematopoietic reconstitution. PharmaStem's contribution was to provide experimental proof that umbilical cord and placental blood could be used to effect hematopoietic reconstitution in mice. By extrapolation, one of ordinary skill in the art would have expected this reconstitution method to work in humans as well.

The court rejected PharmaStem's expert testimony that hematopoietic stem cells had not been proved to exist in cord blood prior to the experiments described in PharmaStem's patents. The court explained that the expert testimony was contrary to the inventors' admissions in the specification, as well as prior art teachings that disclosed stem cells in cord blood. In this case, PharmaStem's evidence of nonobviousness was outweighed by contradictory evidence.

Despite PharmaStem's useful experimental validation of hematopoietic reconstitution using hematopoietic stem cells from umbilical cord and placental blood, the Federal Circuit found that the claims at issue would have been obvious. There had been ample suggestion in the prior art that the claimed method would have worked. Absolute predictability is not a necessary prerequisite to a case of obviousness. Rather, a degree of predictability that one of ordinary skill would have found to be reasonable is sufficient. The Federal Circuit concluded that "[g]ood science and useful contributions do not necessarily result in patentability." *Id.* at 1364.

Example 5.2. In re Sullivan, 498 F.3d 1345 (Fed. Cir. 2007). *Teaching point:* All evidence, including evidence rebutting a *prima facie* case of obviousness, must be considered when properly presented.

It was found to be an error in *Sullivan* for the Board to fail to consider evidence submitted to rebut a *prima facie* case of obviousness.

The claimed invention was directed to an antivenom composition comprising F(ab) fragments used to treat venomous rattlesnake bites. The composition was created from antibody molecules that include three fragments, $F(ab)_2$, F(ab) and F(c), which have separate properties and utilities. There have been commercially available antivenom products that consisted of whole antibodies and $F(ab)_2$ fragments, but researchers had not experimented with antivenoms containing only F(ab) fragments because it was believed that their unique properties would prevent them from decreasing the toxicity of snake venom. The inventor, Sullivan, discovered that F(ab) fragments are effective at neutralizing the lethality of rattlesnake venom, while reducing the occurrence of adverse immune reactions in humans. On appeal of the examiner's rejection, the Board held that the claim was obvious because all the elements of the claimed composition were accounted for in the prior art, and that the composition taught by that prior art would have been expected by a person of ordinary skill in the art at the time the invention was made to neutralize the lethality of the venom of a rattlesnake.

Rebuttal evidence had not been considered by the Board because it

considered the evidence to relate to the intended use of the claimed composition as an antivenom, rather than the composition itself. Appellant successfully argued that even if the Board had shown a *prima facie* case of obviousness, the extensive rebuttal evidence must be considered. The evidence included three expert declarations submitted to show that the prior art taught away from the claimed invention, an unexpected property or result from the use of F(ab) fragment antivenom, and why those having ordinary skill in the art expected antivenoms comprising F(ab) fragments to fail. The declarations related to more than the use of the claimed composition. While a statement of intended use may not render a known composition patentable, the claimed composition was not known, and whether it would have been obvious depends upon consideration of the rebuttal evidence. Appellant did not concede that the only distinguishing factor of its composition is the statement of intended use and extensively argued that its claimed composition exhibits the unexpected property of neutralizing the lethality of rattlesnake venom while reducing the occurrence of adverse immune reactions in humans. The Federal Circuit found that such a use and unexpected property cannot be ignored—the unexpected property is relevant and thus the declarations describing it should have been considered.

Nonobviousness can be shown when a person of ordinary skill in the art would not have reasonably predicted the claimed invention based on the prior art, and the resulting invention would not have been expected. All evidence must be considered when properly presented.

Example 5.3. Hearing Components, Inc. v. *Shure Inc.*, 600 F.3d 1357 (Fed. Cir. 2010). *Teaching point:* Evidence that has been properly presented in a timely manner must be considered on the record. Evidence of commercial success is pertinent where a nexus between the success of the product and the claimed invention has been demonstrated.

The case of *Hearing Components* involved a disposable protective covering for the portion of a hearing aid that is inserted into the ear canal. The covering was such that it could be readily replaced by a user as needed.

At the district court, Shure had argued that Hearing Components' patents were obvious over one or more of three different combinations of prior art references. The jury disagreed, and determined that the claims were nonobvious. The district court upheld the jury verdict, stating that in view of the conflicting evidence presented by the parties as to the teachings of the references, motivation to combine, and secondary considerations, the nonobviousness verdict was sufficiently grounded in the evidence.

Shure appealed to the Federal Circuit, but the Federal Circuit agreed with the district court that the jury's nonobviousness verdict had been supported by substantial evidence. Although Shure had argued before the jury that the Carlisle reference taught an ear piece positioned inside the ear canal, Hearing Components' credible witness countered that only the molded duct and not the ear piece itself was taught by Carlisle as being inside the ear canal. On the issue of combining references, Shure's witness had given testimony described as "rather sparse, and lacking in specific details." *Id.* at 1364. In contradistinction, Hearing Components' witness "described particular reasons why one skilled in the art would not have been motivated to combine the references." *Id.* Finally, as to secondary considerations, the Federal Circuit determined that Hearing Components had shown a nexus between the commercial success of its product and the patent by providing evidence that "the licensing fee for a covered product was more than cut in half immediately upon expiration" of the patent.

Although the *Hearing Components* case involves substantial evidence of nonobviousness in a jury verdict, it is nevertheless instructive for Office personnel on the matter of weighing evidence. Office personnel routinely must consider evidence in the form of prior art references, statements in the specification, or declarations under 37 CFR 1.131 or 1.132. Other forms of evidence may also be presented during prosecution. Office personnel are reminded that evidence that has been presented in a timely manner should not be ignored, but rather should be considered on the record. However, not all evidence need be accorded the same weight. In determining the relative weight to accord to rebuttal evidence, considerations such as whether a nexus exists between the claimed invention and the proffered evidence, and whether the evidence is commensurate in scope with the claimed invention, are appropriate. The mere presence of some credible rebuttal evidence does not dictate that an obviousness rejection must always be withdrawn. *See* MPEP § 2145. Office personnel must consider the appropriate weight to be accorded to each piece of evidence. An obviousness rejection should be made or maintained only if evidence of obviousness outweighs evidence of nonobviousness. *See* MPEP § 706(I) ("The standard to be applied in all cases is the 'preponderance of the evidence' test. In other words, an examiner should reject a claim if, in view of the prior art and evidence of record, it is more likely than not that the claim is unpatentable."). MPEP § 716.01(d) provides further guidance on weighing evidence in making a determination of patentability.

Example 5.4. Asyst Techs., Inc. v. *Emtrak, Inc.*, 544 F.3d 1310 (Fed. Cir. 2008). *Teaching point:* Evidence of secondary considerations of obviousness such as commercial success and long-felt need may be insufficient to overcome a *prima facie* case of obviousness if the *prima facie* case is strong. An argument for nonobviousness based on commercial success or long-felt need is undermined when there is a failure to link the commercial success or long-felt need to a claimed feature that distinguishes over the prior art.

The claims at issue in *Asyst* concerned a processing system for tracking articles such as silicon wafers which move from one processing station to the next in a manufacturing facility. The claims required that each processing station be in communication with a central control unit. The Federal Circuit agreed with the district court that the only difference between the claimed invention and the prior art to Hesser was that the prior art had taught the use of a bus for this communication, while the claims required a multiplexer. At trial, the jury had concluded that Hesser was not relevant prior art, but the district court overturned that conclusion and issued a judgment as a matter of law (JMOL) that the claims would have been obvious in view of Hesser. Because the evidence showed that persons of ordinary skill in the art would have been familiar with both the bus and the multiplexer, and that they could have readily selected and employed one or the other based on known considerations, the Federal Circuit affirmed the district court's conclusion that the claims were invalid for obviousness.

The Federal Circuit also discussed arguments that the district court had failed to consider the objective evidence of nonobviousness presented by Asyst. Asyst had offered evidence of commercial success of its invention. However, the Federal Circuit pointed out that Asyst had not provided the required nexus between the commercial success and the claimed invention, emphasizing that "Asyst's failure to link that commercial success to the features

of its invention that were not disclosed in Hesser undermines the probative force of the evidence * * *." *Id.* at 1316. Asyst had also offered evidence from others in the field praising the invention as addressing a long-felt need. Once again, the Federal Circuit found the argument to be unavailing in view of the prior art, stating that "[w]hile the evidence shows that the overall system drew praise as a solution to a felt need, there was no evidence that the success * * * was attributable to the substitution of a multiplexer for a bus, which was the only material difference between Hesser and the patented invention." *Id.* The Federal Circuit also reiterated, citing pre-*KSR* decisions, that "as we have often held, evidence of secondary considerations does not always overcome a strong *prima facie* showing of obviousness." *Id.* (citing *Pfizer, Inc.* v. *Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007); *Ryko Mfg. Co.* v. *Nu-Star, Inc.*, 950 F.2d 714, 719–20 (Fed. Cir. 1991); *Newell Cos.* v. *Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988)).

When considering obviousness, Office personnel should carefully weigh any properly presented objective evidence of nonobviousness against the strength of the *prima facie* case. If the asserted evidence, such as commercial success or satisfaction of a long-felt need, is attributable to features already in the prior art, the probative value of the evidence is reduced.

6. *Conclusion.* This *2010 KSR Guidelines Update* is intended to be used by Office personnel in conjunction with the guidance provided in MPEP §§ 2141 and 2143 (which incorporates the *2007 KSR Guidelines)* to clarify the contours of obviousness after *KSR*. It addresses a number of issues that arise when Office personnel consider whether or not a claimed invention is obvious. While Office personnel are encouraged to make use of these tools, they are reminded that every question of obviousness must be decided on its own facts. The Office will continue to monitor the developing law of obviousness, and will provide additional guidance and updates as necessary.

Dated: August 20, 2010.

David J. Kappos,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

Appendix

The following table contains the cases set out as examples in this *2010 KSR Guidelines Update* and the teaching points of the case.

Case	Teaching point
Combining Prior Art Elements	
In re Omeprazole Patent Litigation, 536 F.3d 1361 (Fed. Cir. 2008).	Even where a general method that could have been applied to make the claimed product was known and within the level of skill of the ordinary artisan, the claim may nevertheless be nonobvious if the problem which had suggested use of the method had been previously unknown.
Crocs, Inc. v. *U.S. Int'l Trade Comm'n.*, 598 F.3d 1294 (Fed. Cir. 2010).	A claimed combination of prior art elements may be nonobvious where the prior art teaches away from the claimed combination and the combination yields more than predictable results.
Sundance, Inc. v. *DeMonte Fabricating Ltd.*, 550 F.3d 1356 (Fed. Cir. 2008).	A claimed invention is likely to be obvious if it is a combination of known prior art elements that would reasonably have been expected to maintain their respective properties or functions after they have been combined.
Ecolab, Inc. v. *FMC Corp.*, 569 F.3d 1335 (Fed. Cir. 2009).	A combination of known elements would have been *prima facie* obvious if an ordinarily skilled artisan would have recognized an apparent reason to combine those elements and would have known how to do so.
Wyers v. *Master Lock Co.*, No. 2009–1412, —F.3d—, 2010 WL 2901839 (Fed. Cir. July 22, 2010).	The scope of analogous art is to be construed broadly and includes references that are reasonably pertinent to the problem that the inventor was trying to solve. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.
DePuy Spine, Inc. v. *Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009).	Predictability as discussed in *KSR* encompasses the expectation that prior art elements are capable of being combined, as well as the expectation that the combination would have worked for its intended purpose. An inference that a claimed combination would not have been obvious is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.
Substituting One Known Element for Another	
In re ICON Health & Fitness, Inc., 496 F.3d 1374 (Fed. Cir. 2007).	When determining whether a reference in a different field of endeavor may be used to support a case of obviousness (*i.e.*, is analogous), it is necessary to consider the problem to be solved.
Agrizap, Inc. v. *Woodstream Corp.*, 520 F.3d 1337 (Fed. Cir. 2008).	Analogous art is not limited to references in the field of endeavor of the invention, but also includes references that would have been recognized by those of ordinary skill in the art as useful for applicant's purpose.
Muniauction, Inc. v. *Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008).	Because Internet and Web browser technologies had become commonplace for communicating and displaying information, it would have been obvious to adapt existing processes to incorporate them for those functions.
Aventis Pharma Deutschland v. *Lupin, Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007).	A chemical compound would have been obvious over a mixture containing that compound as well as other compounds where it was known or the skilled artisan had reason to believe that some desirable property of the mixture was derived in whole or in part from the claimed compound, and separating the claimed compound from the mixture was routine in the art.
Eisai Co. Ltd. v. *Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008).	A claimed compound would not have been obvious where there was no reason to modify the closest prior art lead compound to obtain the claimed compound and the prior art taught that modifying the lead compound would destroy its advantageous property. Any known compound may serve as a lead compound when there is some reason for starting with that lead compound and modifying it to obtain the claimed compound.
Procter & Gamble Co. v. *Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989 (Fed. Cir. 2009).	It is not necessary to select a single compound as a "lead compound" in order to support an obviousness rejection. However, where there was reason to select and modify the lead compound to obtain the claimed compound, but no reasonable expectation of success, the claimed compound would not have been obvious.

Case	Teaching point
Altana Pharma AG v. *Teva Pharms. USA, Inc.*, 566 F.3d 999 (Fed. Cir. 2009).	Obviousness of a chemical compound in view of its structural similarity to a prior art compound may be shown by identifying some line of reasoning that would have led one of ordinary skill in the art to select and modify a prior art lead compound in a particular way to produce the claimed compound. It is not necessary for the reasoning to be explicitly found in the prior art of record, nor is it necessary for the prior art to point to only a single lead compound.
The Obvious To Try Rationale	
In re Kubin, 561 F.3d 1351 (Fed. Cir. 2009).	A claimed polynucleotide would have been obvious over the known protein that it encodes where the skilled artisan would have had a reasonable expectation of success in deriving the claimed polynucleotide using standard biochemical techniques, and the skilled artisan would have had a reason to try to isolate the claimed polynucleotide. *KSR* applies to all technologies, rather than just the "predictable" arts.
Takeda Chem. Indus. v. *Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).	A claimed compound would not have been obvious where it was not obvious to try to obtain it from a broad range of compounds, any one of which could have been selected as the lead compound for further investigation, and the prior art taught away from using a particular lead compound, and there was no predictability or reasonable expectation of success in making the particular modifications necessary to transform the lead compound into the claimed compound.
Ortho-McNeil Pharmaceutical, Inc. v. *Mylan Labs, Inc.*, 520 F.3d 1358 (Fed. Cir. 2008).	Where the claimed anti-convulsant drug had been discovered somewhat serendipitously in the course of research aimed at finding a new anti-diabetic drug, it would not have been obvious to try to obtain a claimed compound where the prior art did not present a finite and easily traversed number of potential starting compounds, and there was no apparent reason for selecting a particular starting compound from among a number of unpredictable alternatives.
Bayer Schering Pharma A.G. v. *Barr Labs., Inc.*, 575 F.3d 1341 (Fed. Cir. 2009).	A claimed compound would have been obvious where it was obvious to try to obtain it from a finite and easily traversed number of options that was narrowed down from a larger set of possibilities by the prior art, and the outcome of obtaining the claimed compound was reasonably predictable.
Sanofi-Synthelabo v. *Apotex, Inc.*, 550 F.3d 1075 (Fed. Cir. 2008).	A claimed isolated stereoisomer would not have been obvious where the claimed stereoisomer exhibits unexpectedly strong therapeutic advantages over the prior art racemic mixture without the correspondingly expected toxicity, and the resulting properties of the enantiomers separated from the racemic mixture were unpredictable.
Rolls-Royce, PLC v. *United Technologies Corp.*, 603 F.3d 1325 (Fed. Cir. 2010).	An obvious to try rationale may be proper when the possible options for solving a problem were known and finite. However, if the possible options were not either known or finite, then an obvious to try rationale cannot be used to support a conclusion of obviousness.
Perfect Web Techs., Inc. v. *InfoUSA, Inc.*, 587 F.3d 1324 (Fed. Cir. 2009).	Where there were a finite number of identified, predictable solutions and there is no evidence of unexpected results, an obvious to try inquiry may properly lead to a legal conclusion of obviousness. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.
Consideration of Evidence	
PharmaStem Therapeutics, Inc. v. *ViaCell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007).	Even though all evidence must be considered in an obviousness analysis, evidence of nonobviousness may be outweighed by contradictory evidence in the record or by what is in the specification. Although a reasonable expectation of success is needed to support a case of obviousness, absolute predictability is not required.
In re Sullivan, 498 F.3d 1345 (Fed. Cir. 2007).	All evidence, including evidence rebutting a *prima facie* case of obviousness, must be considered when properly presented.
Hearing Components, Inc. v. *Shure Inc.*, 600 F.3d 1357 (Fed. Cir. 2010).	Evidence that has been properly presented in a timely manner must be considered on the record. Evidence of commercial success is pertinent where a nexus between the success of the product and the claimed invention has been demonstrated.
Asyst Techs., Inc. v. *Emtrak, Inc.*, 544 F.3d 1310 (Fed. Cir. 2008).	Evidence of secondary considerations of obviousness such as commercial success and long-felt need may be insufficient to overcome a *prima facie* case of obviousness if the *prima facie* case is strong. An argument for nonobviousness based on commercial success or long-felt need is undermined when there is a failure to link the commercial success or long-felt need to a claimed feature that distinguishes over the prior art.

[FR Doc. 2010–21646 Filed 8–31–10; 8:45 am]
BILLING CODE P

EXHIBIT 11

567 F.3d 1314, 90 U.S.P.Q.2d 1865
(Cite as: 567 F.3d 1314)

▷

United States Court of Appeals,
Federal Circuit.
DEPUY SPINE, INC. (formerly known as Depuy Acromed, Inc.), Plaintiff-Cross Appellant,
and
Biedermann Motech GmbH, Plaintiff-Cross Appellant,
v.
MEDTRONIC SOFAMOR DANEK, INC. (formerly known as Sofamor Danek Group, Inc.) and Medtronic Sofamor Danek USA, Inc., Defendants-Appellants.
Nos. 2008-1240, 2008-1253, 2008-1401.

Decided June 1, 2009.

Background: Patentee and licensee brought action claiming that several of competitors' products infringed various claims of patent for spinal implant device. The United States District Court for the District of Massachusetts, Edward F. Harrington, Senior District Judge, 526 F.Supp.2d 162, entered judgment for plaintiffs, and 533 F.Supp.2d 243, denied defendants' motion for new trial and judgment as a matter of law and plaintiffs' motion for new trial on royalty damages. Cross-appeals were taken.

Holdings: The Court of Appeals, Linn, Circuit Judge, held that:
(1) hypothetical claim did not ensnare prior art;
(2) jury's finding that no acceptable noninfringing alternative was available during relevant accounting period was supported by substantial evidence;
(3) patentee was not legally entitled to recover lost profits on unpatented products;
(4) new trial on issue of reasonable royalty rate was not warranted; and
(5) attorney fee award was not warranted as sanction for conduct during litigation.

Affirmed in part, reversed in part, and remanded.

West Headnotes

[1] Patents 291 ⚿237

291 Patents
291XII Infringement
291XII(A) What Constitutes Infringement
291k233 Patents for Machines or Manufactures
291k237 k. Substitution of Equivalents. Most Cited Cases
Ensnarement bars a patentee from asserting a scope of equivalency that would encompass, or ensnare, the prior art.

[2] Federal Courts 170B ⚿776

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)1 In General
170Bk776 k. Trial De Novo. Most Cited Cases
The constitutional question of whether a party is entitled to a jury trial is a question of law that the Court of Appeals reviews de novo.

[3] Patents 291 ⚿237

291 Patents
291XII Infringement
291XII(A) What Constitutes Infringement
291k233 Patents for Machines or Manufactures
291k237 k. Substitution of Equivalents. Most Cited Cases
Ensnarement, like prosecution history estoppel, limits the scope of equivalency that a patentee is allowed to assert; this limitation is imposed even if a jury has found equivalence as to each claim element.

[4] Patents 291 ⚿237

291 Patents

EXHIBIT 11

291XII Infringement
291XII(A) What Constitutes Infringement
291k233 Patents for Machines or Manufactures
291k237 k. Substitution of Equivalents. Most Cited Cases
The ensnarement inquiry is separate and distinct from the jury's element-by-element equivalence analysis on patent infringement claims, and it has no bearing on the validity of the actual claims.

[5] Patents 291 ⚿312(1.1)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k312 Evidence
291k312(1) Presumptions and Burden of Proof
291k312(1.1) k. In General. Most Cited Cases

Patents 291 ⚿312(1.6)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k312 Evidence
291k312(1) Presumptions and Burden of Proof
291k312(1.6) k. Laches and Estoppel. Most Cited Cases
In analyses of ensnarement and prosecution history estoppel in patent infringement action, the burden of persuasion is on the patentee to establish either that the reason for the amendment was unrelated to patentability, or that the asserted scope of equivalency would not ensnare the prior art.

[6] Patents 291 ⚿314(5)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k314 Hearing
291k314(5) k. Questions of Law or Fact. Most Cited Cases
Ensnarement, like prosecution history estoppel, is to be determined by the court in a patent infringement action, either on a pretrial motion for partial summary judgment or on a motion for judgment as a matter of law at the close of the evidence and after the jury verdict.

[7] Patents 291 ⚿168(2.1)

291 Patents
291IX Construction and Operation of Letters Patent
291IX(B) Limitation of Claims
291k168 Proceedings in Patent Office in General
291k168(2) Rejection and Amendment of Claims
291k168(2.1) k. In General. Most Cited Cases
When deciding whether an equivalent would have been unforeseeable, as required for prosecution history estoppel in a patent infringement action, a district court may hear expert testimony and consider other extrinsic evidence relating to the relevant factual inquiries, including the state of the art and the understanding of a hypothetical person of ordinary skill in the art at the time of the amendment.

[8] Patents 291 ⚿237

291 Patents
291XII Infringement
291XII(A) What Constitutes Infringement
291k233 Patents for Machines or Manufactures
291k237 k. Substitution of Equivalents. Most Cited Cases
A district court determining ensnarement in a patent infringement action may hear expert testimony and consider other extrinsic evidence regarding: (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention, (3) the level of ordinary skill in the art, and (4) any relevant secondary considerations.

[9] Patents 291 ⚿314(6)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k314 Hearing
291k314(6) k. Findings and Determination. Most Cited Cases
If a district court believes that an advisory verdict from the jury would be helpful, and that a hypothetical claim construct would not unduly confuse the jury as to equivalence and validity, then one may be obtained under rule governing advisory juries. Fed.Rules Civ.Proc.Rule 39(c), 28 U.S.C.A.

[10] Patents 291 ⚿324.5

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k324 Appeal
291k324.5 k. Scope and Extent of Review in General. Most Cited Cases
Court of Appeals reviews de novo the district court's conclusion in a patent infringement action that a hypothetical claim does not ensnare the prior art.

[11] Patents 291 ⚿324.55(5)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k324 Appeal
291k324.55 Questions of Fact, Verdicts, and Findings
291k324.55(5) k. Issues of Infringement. Most Cited Cases
Court of Appeals reviews a district court's resolution in a patent infringement action of the underlying factual issues in the ensnarement context for clear error.

[12] Patents 291 ⚿237

291 Patents
291XII Infringement
291XII(A) What Constitutes Infringement
291k233 Patents for Machines or Manufactures
291k237 k. Substitution of Equivalents. Most Cited Cases
A helpful first step in an ensnarement analysis in a patent infringement action is to construct a hypothetical claim that literally covers the accused device.

[13] Patents 291 ⚿237

291 Patents
291XII Infringement
291XII(A) What Constitutes Infringement
291k233 Patents for Machines or Manufactures
291k237 k. Substitution of Equivalents. Most Cited Cases
When performing the ensnarement analysis in a patent infringement action, the district court must assess the prior art introduced by the accused infringer and determine whether the patentee has carried its burden of persuading the court that the hypothetical claim is patentable over the prior art.

[14] Patents 291 ⚿237

291 Patents
291XII Infringement
291XII(A) What Constitutes Infringement
291k233 Patents for Machines or Manufactures
291k237 k. Substitution of Equivalents. Most Cited Cases
If a hypothetical claim asserted under doctrine of equivalents would be unpatentable, then the patentee has overreached, and the accused device is noninfringing as a matter of law. 35 U.S.C.A. §§ 102, 103.

[15] Patents 291 ⚿26(1.1)

291 Patents
291II Patentability
291II(A) Invention; Obviousness

291k26 Combination
291k26(1.1) k. Use of Old or Well-Known Elements. Most Cited Cases
In a patent infringement action, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

[16] Patents 291 ⚿16.5(1)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.5 State of Prior Art and Advancement Therein
291k16.5(1) k. In General. Most Cited Cases

Patents 291 ⚿26(1.1)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k26 Combination
291k26(1.1) k. Use of Old or Well-Known Elements. Most Cited Cases
In a patent infringement action, when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious; the opposite conclusion would follow, however, if the prior art indicated that the invention would not have worked for its intended purpose or otherwise taught away from the invention.

[17] Patents 291 ⚿16.5(1)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.5 State of Prior Art and Advancement Therein
291k16.5(1) k. In General. Most Cited Cases
In a patent infringement action, an inference of nonobviousness is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.

[18] Patents 291 ⚿16.14

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.14 k. Miscellaneous Inventions. Most Cited Cases
Hypothetical claim in patent for spinal implant device would not have been obvious in view of combination of alleged prior art, as required for competitors' ensnarement defense to patent infringement claims; prior art taught away from rigid pedicle screws used in spinal implant device, and competitor did not deny copying patent's compression member concept in accused device after attempting to make rigid pedicle screw without compression member.

[19] Patents 291 ⚿16.5(1)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.5 State of Prior Art and Advancement Therein
291k16.5(1) k. In General. Most Cited Cases
For patent infringement purposes, a reference may be said to "teach away" when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.

[20] Patents 291 ⚿16.5(1)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.5 State of Prior Art and Advancement Therein

291k16.5(1) k. In General. Most Cited Cases

For patent infringement purposes, a reference does not "teach away" if it merely expresses a general preference for an alternative invention but does not criticize, discredit, or otherwise discourage investigation into the invention claimed.

[21] Courts 106 ⚿96(7)

106 Courts
106II Establishment, Organization, and Procedure
106II(G) Rules of Decision
106k88 Previous Decisions as Controlling or as Precedents
106k96 Decisions of United States Courts as Authority in Other United States Courts
106k96(7) k. Particular Questions or Subject Matter. Most Cited Cases

Court of Appeals for the Federal Circuit reviews the district court's denial of a motion for judgment as a matter of law under the law of the regional circuit in which an appeal from the district court would usually lie.

[22] Federal Courts 170B ⚿776

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)1 In General
170Bk776 k. Trial De Novo. Most Cited Cases

In the First Circuit, the district court's decision to grant or deny a motion for judgment as a matter of law is reviewed de novo. Fed.Rules Civ.Proc.Rule 50(a)(1), 28 U.S.C.App.(2006 Ed.)

[23] Patents 291 ⚿318(1)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k318 Profits
291k318(1) k. In General. Most Cited Cases

The four-factor *Panduit* test, used to advance a lost-profits theory in patent infringement action, requires a showing of (1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) manufacturing and marketing capability to exploit the demand, and (4) the amount of profit that would have been made.

[24] Patents 291 ⚿318(1)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k318 Profits
291k318(1) k. In General. Most Cited Cases

Demand for patentee's pedicle screws was driven by screws' "top-loading" feature, as required for lost profits analysis in patent infringement action; demand generally existed for patented pedicle screws, and demand for those screws was driven primarily by their polyaxial capability, a feature inherent in both competitors' accused screws and patentee's screws.

[25] Patents 291 ⚿318(1)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k318 Profits
291k318(1) k. In General. Most Cited Cases

When evaluating lost profits in a patent infringement action, the focus on particular features corresponding to individual claim limitations is unnecessary when considering whether demand exists for a patented product under the first *Panduit* factor, demand for the patented product; rather, the elimination or substitution of particular features corresponding to one or more claim limitations goes to the availability of acceptable noninfringing substitutes under the second *Panduit* factor, absence of acceptable noninfringing substitutes.

[26] Patents 291 ⚿312(10)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k312 Evidence
291k312(3) Weight and Sufficiency
291k312(10) k. Profits and Damages. Most Cited Cases

Jury's finding in patent infringement action that no acceptable noninfringing alternative to pedicle screws was available during relevant accounting period was supported by substantial evidence, as required for determination of lost profits; patentee presented evidence of competitors' three unsuccessful attempts to develop noninfringing, bottom-loading design.

[27] Patents 291 ⚿312(2)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k312 Evidence
291k312(2) k. Admissibility. Most Cited Cases

Probative value of district court's prior summary judgment ruling that top-loading screw model did not infringe patent for spinal implant device was low compared to risk of jury confusion, and thus it was within district court's discretion to exclude evidence of prior ruling from lost profits analysis in patent infringement action, although district court's favorable ruling might have been the reason that competitor felt content to wait to develop noninfringing, bottom-loading version of screw; summary judgment ruling would not have addressed why competitor had failed three times to overcome various technical and regulatory hurdles in achieving noninfringing design, if ruling was admitted into evidence court would have had to explain to jury that court had previously decided infringement issue, that decision was overruled in part with regard to equivalence but not literal infringement, and that jury was required to ignore evidence when deciding equivalence for itself but could later consider it when assessing damages.

[28] Patents 291 ⚿324.5

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k324 Appeal
291k324.5 k. Scope and Extent of Review in General. Most Cited Cases

Whether lost profits are legally compensable in a particular patent situation is a question of law that the Court of Appeals reviews de novo.

[29] Patents 291 ⚿318(4.1)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k318 Profits
291k318(4) Entire Profits or Those Attributable to Infringement of Patent
291k318(4.1) k. In General. Most Cited Cases

A patentee may recover lost profits on unpatented components sold with a patented item, a convoyed sale, if both the patented and unpatented products together were considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit; in contrast to such functionally-integrated components that are properly subject to lost profits, there is no basis for extending that recovery to include damages for unpatented items that are neither competitive with nor function with the patented invention.

[30] Patents 291 ⚿318(4.1)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k318 Profits
291k318(4) Entire Profits or Those Attributable to Infringement of Patent
291k318(4.1) k. In General. Most Cited Cases

Lost profits cannot be recovered on unpatented items that have essentially no functional relationship to the patented invention and that may have been sold with an infringing device only as a matter of convenience or business advantage.

[31] Patents 291 ⚿318(4.1)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k318 Profits
291k318(4) Entire Profits or Those Attributable to Infringement of Patent
291k318(4.1) k. In General. Most Cited Cases
Patentee's unpatented pull-through products neither competed nor functioned with its patented spinal implant devices and were sold only by virtue of patentee's business relationship with surgeons, and thus patentee was not legally entitled to recover lost profits on unpatented products.

[32] Patents 291 ⚿323.3

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k323 Final Judgment or Decree
291k323.3 k. Relief from Judgment or Decree. Most Cited Cases
New trial on issue of reasonable royalty rate in patent infringement action was not warranted, although jury award of 0% reasonable royalty rate on infringing sales rendered verdict inconsistent; patentee was aware of issue, could have properly objected, and failed to timely object to inconsistency.

[33] Courts 106 ⚿96(7)

106 Courts
106II Establishment, Organization, and Procedure
106II(G) Rules of Decision
106k88 Previous Decisions as Controlling or as Precedents
106k96 Decisions of United States Courts as Authority in Other United States Courts
106k96(7) k. Particular Questions or Subject Matter. Most Cited Cases
Court of Appeals for the Federal Circuit reviews decisions on motions for a new trial under the law of the regional circuit.

[34] Federal Courts 170B ⚿825.1

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)4 Discretion of Lower Court
170Bk825 New Trial or Rehearing
170Bk825.1 k. In General. Most Cited Cases
The First Circuit reviews the denial of a motion for new trial for an abuse of discretion.

[35] Patents 291 ⚿312(8)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k312 Evidence
291k312(3) Weight and Sufficiency
291k312(8) k. Participation, Intent, and Contributory Infringement. Most Cited Cases
There was no legally sufficient evidentiary basis in patent infringement action to find objectively high likelihood under first prong of willfulness test that allegedly infringing model, which contained conically-shaped portion, infringed patent for spinal implant device, whose claims recited "spherically-shaped portion"; accused device did not literally infringe patent, and there was substantial question of noninfringement under doctrine of equivalents.

[36] Patents 291 ⚿227

291 Patents
291XII Infringement
291XII(A) What Constitutes Infringement
291k227 k. Intent or Purpose, and Know-

ledge. Most Cited Cases
First prong of *Seagate* standard used to determine willfulness of patent infringement is objective, and the state of mind of the accused infringer is not relevant to this objective inquiry.

[37] Patents 291 ⚷312(6)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k312 Evidence
291k312(3) Weight and Sufficiency
291k312(6) k. Particular Matters, Sufficiency as To. Most Cited Cases
Evidence of copying is of no import on the question of whether the claims of an issued patent are infringed, either literally or by equivalents; evidence of copying in a case of direct infringement is relevant only to the second prong used to determine willfulness of patent infringement, as it may show what the accused infringer knew or should have known about the likelihood of its infringement.

[38] Patents 291 ⚷324.5

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k324 Appeal
291k324.5 k. Scope and Extent of Review in General. Most Cited Cases

Patents 291 ⚷324.54

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k324 Appeal
291k324.54 k. Presumptions and Discretion of Lower Court. Most Cited Cases

Patents 291 ⚷324.55(2)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k324 Appeal
291k324.55 Questions of Fact, Verdicts, and Findings
291k324.55(2) k. Clearly Erroneous Findings. Most Cited Cases
Where a district court finds a patent infringement case exceptional, the Court of Appeals reviews the underlying factual findings for clear error and legal conclusions without deference; once the district court has found a case to be exceptional, the Court of Appeals reviews any award of attorney fees for an abuse of discretion. 35 U.S.C.A. § 285.

[39] Federal Courts 170B ⚷813

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)4 Discretion of Lower Court
170Bk813 k. Allowance of Remedy and Matters of Procedure in General. Most Cited Cases
A court's exercise of its inherent powers is reviewed for an abuse of discretion.

[40] Patents 291 ⚷237

291 Patents
291XII Infringement
291XII(A) What Constitutes Infringement
291k233 Patents for Machines or Manufactures
291k237 k. Substitution of Equivalents. Most Cited Cases
The reverse doctrine of equivalents, like the doctrine of equivalents, is applied to individual limitations of a patent claim.

[41] Patents 291 ⚷325.11(3)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k325 Costs
291k325.11 Disbursements in General
291k325.11(2) Attorney Fees

291k325.11(3) k. Award to Plaintiff. Most Cited Cases
Competitors' arguments in patent infringement action were not baseless, frivolous, or intended primarily to mislead jury, and thus case was not exceptional, as required for attorney fee award as sanction in favor of patentee, although assertion of reverse doctrine of equivalents as defense ultimately failed. 35 U.S.C.A. § 285.

[42] Patents 291 ⚿325.11(3)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k325 Costs
291k325.11 Disbursements in General
291k325.11(2) Attorney Fees
291k325.11(3) k. Award to Plaintiff. Most Cited Cases
Sua sponte imposition of $10 million sanction for competitors' reliance on reverse doctrine of equivalents as defense to patent infringement was not warranted, absent finding that competitors' arguments were baseless, frivolous, or intended primarily to mislead jury.

[43] Interest 219 ⚿39(3)

219 Interest
219III Time and Computation
219k39 Time from Which Interest Runs in General
219k39(3) k. Interest from Date of Judgment or Decree. Most Cited Cases
In the First Circuit, post-judgment interest accrues from the initial entry of the district court's judgment on the jury verdict, not from the denial of post-judgment motions.

Patents 291 ⚿328(2)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(2) k. Original Utility. Most Cited Cases
2,346,346, 4,805,602, 4,946,458, 5,207,678, 5,474,555. Cited.

***1319** Calvin P. Griffith, Jones Day, of Cleveland, OH, argued for all plaintiffs-cross appellants. With him on the brief for Depuy Spine, Inc. (formerly know as Depuy Acromed, Inc.), were Patrick J. Norton; and Gregory A. Castanias, of Washington, DC. On the brief for Biedermann Motech GmbH were Luke L. Dauchot and Greer N. Shaw, Kirkland & Ellis LLP, of Los Angeles, CA.

Seth P. Waxman, Wilmer Cutler Pickering Hale and Dorr LLP, of Washington, DC, argued for defendants-appellants. With him on the brief were William G. McElwain; and Mark C. Fleming, Richard W. O'Neill, Timothy R. Shannon, Lauren B. Fletcher, and Sydenham B. Alexander, III, of Boston, MA. Of counsel on the brief were Dirk D. Thomas, André J. Bahou, and John K. Warren, Dewey & LeBoeuf LLP, of Washington, DC.

Before NEWMAN, BRYSON, and LINN, Circuit Judges.

LINN, Circuit Judge.

Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively "Medtronic") appeal from a final judgment of the United States District Court for the District of Massachusetts. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, No. 01-CV-10165 (D.Mass. Dec.11, 2007). The district court denied Medtronic's ensnarement defense after a jury found that Medtronic had infringed U.S. Patent No. 5,207,678 ("the '678 patent") under the doctrine of equivalents and awarded $226.3 million in lost-profit damages to DePuy Spine, Inc. and Biedermann Motech GmbH (collectively "DePuy"). *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 526 F.Supp.2d 162 (D.Mass.2007) (" *Ensnarement Order* "). The district court also found that Medtronic had engaged in

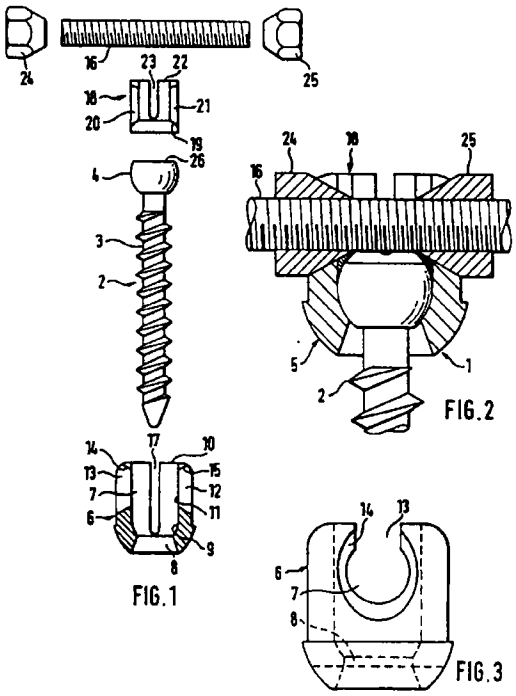
litigation misconduct, for which the court awarded DePuy $425,375 in attorney fees under 35 U.S.C. § 285 and imposed a further $10 million sanction against Medtronic under the court's inherent authority. *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 534 F.Supp.2d 224 (D.Mass.2008) (" *Sanctions Order*"). DePuy cross-appeals from the grant of ***1320** Medtronic's motion for judgment as a matter of law ("JMOL") of no willful infringement and from the denial of DePuy's motion for new trial on reasonable royalty damages.

Because the district court correctly denied Medtronic's ensnarement defense and correctly denied Medtronic's motion for JMOL on lost profits of patented pedicle screws, we affirm the damages award as to those products. However, we reduce the damages award insofar as the lost profits were based partly on lost sales of unpatented "pull-through" products, which neither compete nor function with the patented invention. We also reverse the award of attorney fees and the imposition of sanctions, which were predicated on a legal error involving the application of the reverse doctrine of equivalents. Finally, we conclude that the district court correctly determined that Medtronic was entitled to JMOL of no willfulness, and that it did not abuse its discretion in denying DePuy's motion for new trial on royalty damages. Thus, we affirm-in-part, reverse-in-part, and remand for calculation of post-judgment interest.

BACKGROUND

This appeal involves Medtronic's Vertex® model of polyaxial pedicle screws used in spinal surgeries. In a prior appeal, we affirmed the district court's grant of summary judgment of no literal infringement of the '678 patent by the Vertex® model, but reversed the grant of summary judgment of noninfringement under the doctrine of equivalents. *DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc.*, No. 01-CV-10165 (D.Mass. Feb.24, 2004), *aff'd in part, rev'd in part sub nom. DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1026 (Fed.Cir.2006) (*"DePuy Spine I "*). We held that the Vertex® model, which contains a receiver member having an inner hollow space that is conical in shape, does not literally infringe because it does not meet the "spherically-shaped" limitation of claim 1. 469 F.3d at 1016. However, we concluded that a question of fact existed as to whether the Vertex® model's conical shape was insubstantially different from the claimed "spherically-shaped portion" under the doctrine of equivalents, and remanded for resolution of that issue. *Id.* at 1020. The patented device, as shown below in figures 1 through 3 of the '678 patent, includes a pedicle screw **1** having a screw head **4** that is surrounded by the *spherically-shaped portion* **9** of the receiver member **5:**

***1321**



On remand, Medtronic raised an "ensnarement" defense against the doctrine of equivalents, arguing that the asserted scope of equivalency would encompass, or "ensnare," the prior art. Specifically, Medtronic argued that the combination of U.S. Patent No. 5,474,555 ("Puno") and U.S. Patent No. 2,346,346 ("Anderson") would have rendered obvious a "hypothetical" version of claim 1 of the '678 patent, in which the phrase "conically-shaped" is substituted for the actual claim term "spherically-shaped." The district court took the question from the jury and held that ensnarement, like prosecution history estoppel, is a legal limitation on the doctrine of equivalents that would be decided by the court at the conclusion of the infringement proceeding. *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 515 F.Supp.2d 206 (D.Mass.2007).

A two-week jury trial was held on the issues of infringement, willfulness, and damages. At the close of evidence, the district court granted Medtronic's motion for JMOL of no willfulness. The case then went to the jury on infringement and damages. The jury, using a special verdict form, found that the Vertex® model infringed independent claim 1 and dependent claims 3, 5, and 6 of the '678 patent under the doctrine of equivalents, and awarded DePuy a total of $226.3 million in damages consisting of $149.1 million in lost profits on pedicle screws and $77.2 million in lost profits on "pull-through" products. But the jury awarded DePuy a 0% royalty rate on $237.2 million worth of infringing sales that were not subject to DePuy's claim for lost profits, even though Medtronic itself had argued for no less than a 6% royalty rate if its products were found to infringe. After the jury was dismissed, the district court denied Medtronic's post-trial motions for a new trial on infringement and for JMOL on lost profits. *1322*Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 533 F.Supp.2d 243 (D.Mass.2008) (" *Feb. 6 Order* "). DePuy also filed a post-trial motion seeking a new trial on royalty damages. The district court denied that motion, noting that DePuy had failed to timely object to the inconsistency in the verdict before the jury was dis-

charged. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.,* No. 01-CV-10165 (D.Mass. Feb.14, 2007) ("*Feb. 14 Order* ").

After the jury trial, the district court conducted a separate bench trial on Medtronic's ensnarement defense. In a memorandum and order dated December 11, 2007, the district court held that the combination of Puno and Anderson did not render the hypothetical claim obvious. *Ensnarement Order,* 526 F.Supp.2d at 176. As part of that order, the district court directed entry of judgment on the jury verdict, including the jury determination of $226.3 million in damages. *Id.* at 177. Several months later, in a concurrent reexamination of the '678 patent requested by Medtronic (Control No. 90/008,589), the U.S. Patent & Trademark Office issued a Notice of Intent to Issue an Ex Parte Reexamination Certificate, indicating that all (actual) claims under reexamination were being confirmed over Puno and Anderson without change. A reexamination certificate issued on June 24, 2008.

DePuy next moved for enhanced damages under 35 U.S.C. § 284 and attorney fees under § 285, alleging a "litany" of litigation misconduct on the part of Medtronic. *Sanctions Order,* 534 F.Supp.2d at 225. The district court denied enhanced damages because willful infringement had not been shown. But, because the court perceived Medtronic to have attempted to relitigate at trial its argument from the first appeal regarding the construction of the "pressed against" limitation, in the guise of a reverse doctrine of equivalents defense, the court awarded DePuy 15% of its attorney fees, totaling $425,375. The court stated that Medtronic's reverse doctrine of equivalents defense "threatened to mislead and confuse the jury" and "flouted the governing claim construction as set forth by the Federal Circuit." *Id.* at 226-27. Based on this misconduct, the district court *sua sponte* imposed a further $10 million sanction under the court's inherent authority, remarking in a footnote that "[w]here the amount in controversy in a case is large (as was the case here), the prospective penalty for litigation misconduct, if it is to serve the purpose of deterring that conduct, should also be large." *Id.* at 227 n. 3.

Both parties appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Ensnarement

[1] Ensnarement bars a patentee from asserting a scope of equivalency that would encompass, or "ensnare," the prior art. *See Wilson Sporting Goods Co. v. David Geoffrey & Assoc.,* 904 F.2d 677, 683 (Fed.Cir.1990), *overruled in part on other grounds, Cardinal Chem. Co. v. Morton Int'l, Inc.,* 508 U.S. 83, 92 n. 12, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993). On appeal, Medtronic challenges the district court's denial of its ensnarement defense on the merits. Alternatively, Medtronic argues that it was entitled to present its defense to a jury rather than to the district court. We first address the jury issue and hold that ensnarement, like prosecution history estoppel, is a legal limitation on the doctrine of equivalents to be decided by the court, not a jury. We then conclude that Medtronic's ensnarement defense was properly denied on the merits.

A. The Jury Issue

[2] "The constitutional question of whether a party is entitled to a jury trial is ***1323** a question of law that this court reviews de novo." *Tegal Corp. v. Tokyo Electron Am., Inc.,* 257 F.3d 1331, 1339 (Fed.Cir.2001). Medtronic argues that ensnarement, like infringement, must be tried to a jury when requested by a defendant. Although Medtronic acknowledges that ensnarement is ultimately a question of law, *see Wilson Sporting Goods,* 904 F.2d at 683, Medtronic argues that ensnarement's underlying factual issues must be resolved by a jury if one is requested.

Notwithstanding the jury's proper fact-finding role

in assessing the equivalence of each limitation of a claim, the Supreme Court has recognized "various legal limitations on the application of the doctrine of equivalents." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 39 n. 8, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997). These "legal limitations ... are to be determined *by the court* either on a pretrial motion for partial summary judgment or on a motion for judgment as a matter of law at the close of the evidence and after the jury verdict." *Id.* (emphasis added). In *Warner-Jenkinson,* the Supreme Court identified two such "legal limitations": (1) the "all-elements rule," which bars a patentee from asserting "a theory of equivalence [that] would entirely vitiate a particular claim element," and (2) prosecution history estoppel, which bars a patentee from asserting a scope of equivalency surrendered during prosecution. *Id.* On the issue of prosecution history estoppel, our second en banc *Festo* decision held that "the determinations concerning whether the presumption of surrender has arisen and whether it has been rebutted are questions of law for the court, *not a jury,* to decide." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.,* 344 F.3d 1359, 1368 (Fed.Cir.2003) (en banc) (emphasis added).

[3][4] Although *Warner-Jenkinson* did not explicitly mention "ensnarement" as one of the "various legal limitations on the application of the doctrine of equivalents" to be decided by a court, we have consistently treated it as such. We have called ensnarement and prosecution history estoppel, collectively, "two policy oriented limitations" on the doctrine of equivalents, both of which are "applied as questions of law." *Loctite Corp. v. Ultraseal Ltd.,* 781 F.2d 861, 870 (Fed.Cir.1985), *overruled in part on other grounds, Nobelpharma AB v. Implant Innovations, Inc.,* 141 F.3d 1059, 1068 (Fed.Cir.1998) (en banc). Ensnarement, like prosecution history estoppel, limits the scope of equivalency that a patentee is allowed to assert. This limitation is imposed even if a jury has found equivalence as to each claim element. *See Wilson Sporting Goods,* 904 F.2d at 683 ("Even if this [function-way-result] test is met, however, there can be no infringement if the asserted scope of equivalency of what is literally claimed would encompass the prior art."); *id.* at 687 (deciding ensnarement "as a matter of law" after jury found infringement). The ensnarement inquiry is separate and distinct from the jury's element-by-element equivalence analysis, and it has no bearing on the validity of the actual claims. *See id.* at 685 ("Wilson's claims will remain valid whether or not Wilson persuades us that it is entitled to the range of equivalents sought here.").

[5][6] We see no reason why ensnarement should be treated differently, for procedural purposes, than prosecution history estoppel. As mentioned, both are "legal limitation[s] on the application of the doctrine of equivalents," decided as questions of law, and reviewed de novo. *Festo,* 344 F.3d at 1368; *Wilson Sporting Goods,* 904 F.2d at 683. In both analyses, the burden of persuasion is on the patentee to establish either that the reason for the amendment was unrelated to patentability, ***1324** *Warner-Jenkinson,* 520 U.S at 33, 117 S.Ct. 1040 (prosecution history estoppel), or that the asserted scope of equivalency would not ensnare the prior art, *Wilson Sporting Goods,* 904 F.2d at 685 (ensnarement). Although both analyses "may be subject to underlying facts," we have recognized that "the resolution of factual issues underlying a legal question may properly be decided by the court," *Festo,* 344 F.3d at 1368 n. 3 (prosecution history estoppel), and we review the district court's resolution of those factual issues for clear error, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.,* 493 F.3d 1368, 1376 (Fed.Cir.2007) (prosecution history estoppel). Accordingly, we hold that ensnarement, like prosecution history estoppel, is "to be determined by the court, either on a pretrial motion for partial summary judgment or on a motion for judgment as a matter of law at the close of the evidence and after the jury verdict." *Warner-Jenkinson,* 520 U.S at 39 n. 8, 117 S.Ct. 1040. As a practical matter, both legal limitations may be readily addressed in the same set of mo-

tions.

[7][8][9] For guidance on resolving ensnarement's factual issues, we again draw analogy to prosecution history estoppel, particularly in the context of rebutting the presumption of surrender under the "foreseeability" criterion. *See Festo,* 344 F.3d at 1369 ("This criterion presents an objective inquiry, asking whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the amendment."). In that context, when deciding whether an equivalent would have been unforeseeable, "a district court may hear expert testimony and consider other extrinsic evidence relating to the relevant factual inquiries," including "the state of the art and the understanding of a hypothetical person of ordinary skill in the art at the time of the amendment." *Id.* So too, in the ensnarement context, a district court may hear expert testimony and consider other extrinsic evidence regarding: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art; and (4) any relevant secondary considerations. *Graham v. John Deere Co.,* 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966). If a district court believes that an advisory verdict would be helpful, and that a "hypothetical claim" construct would not unduly confuse the jury as to equivalence and validity, then one may be obtained under Federal Rule of Civil Procedure 39(c). *See, e.g., Interactive Pictures Corp. v. Infinite Pictures, Inc.,* 274 F.3d 1371, 1375 (Fed.Cir.2001) (ensnarement submitted to jury with parties' consent). Ultimately, however, ensnarement is a question of law for the court, not the jury, to decide.

B. The Ensnarement Defense

[10][11] Medtronic argues that the district court erred in holding that hypothetical claim 1 would not have been obvious over a combination of Puno and Anderson. The district court found that Puno "teaches away" from the proposed combination and that various "secondary considerations" support a conclusion of nonobviousness. *Ensnarement Order,* 526 F.Supp.2d at 172-76. We review de novo the district court's conclusion that a hypothetical claim does not ensnare the prior art. *Wilson Sporting Goods,* 904 F.2d at 683. We review a district court's resolution of underlying factual issues in the ensnarement context for clear error. *Cf. Festo,* 493 F.3d at 1376 (applying clear error standard to review of fact-finding underlying "foreseeability" criterion).

[12] A helpful first step in an ensnarement analysis is to construct a hypothetical claim that literally covers the accused device. *Interactive Pictures,* 274 F.3d at 1380. Here, both parties agree that the following hypothetical claim literally covers the Vertex® model:

> ***1325** Device for stabilizing spinal column segments, comprising a pedicle screw (1) having a threaded shaft portion (3) and a spherically-shaped head (4) at the end of said threaded shaft portion, a receiver member (5) flexibly connected to said head (4), said receiver member being provided with two holes for receiving a rod 916) [sic:(16)], a receiver chamber (7) being provided within said receiver member (5), the receiver chamber (7) having at one end thereof a bore (8) for passing the threaded shaft portion (3) therethrough and an inner hollow *conically*-shaped portion (9) for receiving the head (4) of said screw (1), an opening (10) being provided opposite said bore (8) for inserting said screw (1), said device further comprising a compression member (18) for exerting a force onto said head (4) such that said head is pressed against the hollow *conically*-shaped portion (9).

'678 patent, cl.1 (emphases added to denote substitution of "conically" for "spherically").

[13][14] Next, the district court must assess the prior art introduced by the accused infringer and determine whether the patentee has carried its burden of persuading the court that the hypothetical claim is patentable over the prior art. *Interactive Pictures,*

274 F.3d at 1380. Ultimately, "[i]f such a claim would be unpatentable under 35 U.S.C. §§ 102 or 103, then the patentee has overreached, and the accused device is noninfringing as a matter of law." *Id.*

Medtronic produced two references, Puno and Anderson, that it believes renders the hypothetical claim obvious under § 103. Puno discloses a polyaxial pedicle screw assembly, illustrated in figure 7 of Puno, reproduced below left, which the parties agree contains all elements of the claim other than a "compression member" for pressing the screw head against the receiver member. Because Puno's design lacks a compression member, the screw head **30** is separated from the receiver member, depicted in figure 7 as anchor seat **23,** and achieves what Puno calls a "shock absorber" effect, allowing for some motion between the anchor seat and the vertebrae. Puno col.3 ll.60-63. This shock absorber effect "prevent[s] direct transfer of load from the rod to the bone-screw interface prior to achieving bony fusion, thereby decreasing the chance of failure of the screw or the bone-screw interface." *Id.* col.3 ll.64-67. Medtronic asserts that Puno's missing compression member is readily found in Anderson. Anderson discloses an external fracture immobilization splint for immobilizing long bones, such as arm or leg bones, with a swivel clamp that is capable of polyaxial movement until it is rigidly secured by a compression member. The compression member is depicted in figure 4 of Anderson, reproduced below right, as sleeve **15**' having a spherically-curved seat **15'.** Anderson pg.2 col.2 ll.30-37.

***1326**

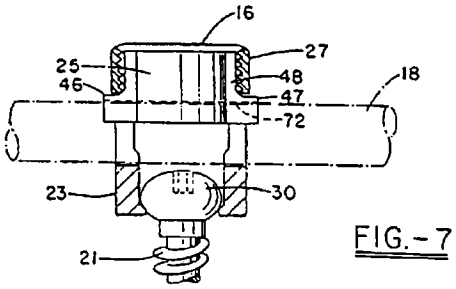
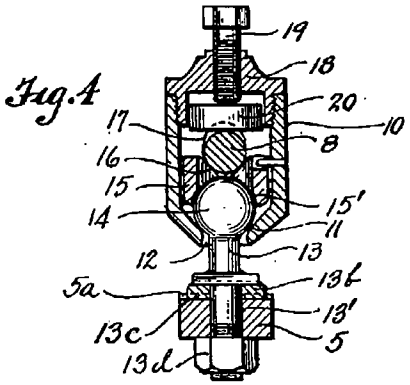


FIG.-7



When asked on cross-examination at the ensnarement hearing whether a person of ordinary skill would have recognized that the addition of Anderson's compression member to Puno's device would have achieved a rigidly-locked polyaxial pedicle screw covered by the hypothetical claim, DePuy's expert answered "I think so." J.A. 5557. Medtronic argues that this admission alone is sufficient to render the hypothetical claim obvious. We disagree.

[15][16][17] Although predictability is a touchstone of obviousness, the "predictable result" discussed in KSR refers not only to the expectation that prior art elements are capable of being physically combined, but also that the combination would have worked for its intended purpose. *KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 127 S.Ct. 1727, 1739-40, 167 L.Ed.2d 705 (2007). As the Supreme Court explained, "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 1739 (emphasis added). The Su-

preme Court went on to state that "when a patent 'simply arranges old elements with each *performing the same function* it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 1740 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282, 96 S.Ct. 1532, 47 L.Ed.2d 784 (1976)) (emphasis added). The opposite conclusion would follow, however, if the prior art indicated that the invention would not have worked for its intended purpose or otherwise taught away from the invention. See *United States v. Adams,* 383 U.S. 39, 52, 86 S.Ct. 708, 15 L.Ed.2d 572 (1966) (upholding nonobviousness where references teaching away from the claimed combination would "deter any investigation into such a combination"); *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1382 (Fed.Cir.2007) ("[A] reference teaches away from a combination when using it in that combination would produce an inoperative result."). An inference of nonobviousness is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.

[18] Here, Medtronic asserts that achieving a rigid pedicle screw was itself the reason to combine Puno and Anderson. In rebuttal, DePuy argues, and the district court found, that Puno "teaches away" from a rigid screw because Puno warns that rigidity increases the likelihood that the screw will fail within the human body, rendering the device inoperative for its ***1327** intended purpose. *Ensnarement Order,* 526 F.Supp.2d at 172. The district court thus found that Puno's teachings undermine the very reason Medtronic proffers as to why it would have been obvious to combine Puno and Anderson, viz., the creation of a rigid screw.

[19][20] "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325, 1332 (Fed.Cir.2008) (quoting *In re Kahn,* 441 F.3d 977, 990 (Fed.Cir.2006)). A reference does not teach away, however, if it merely expresses a general preference for an alternative invention but does not "criticize, discredit, or otherwise discourage" investigation into the invention claimed. *In re Fulton,* 391 F.3d 1195, 1201 (Fed.Cir.2004). In this case, we agree with the district court that Puno does not merely express a general preference for pedicle screws having a "shock absorber" effect. Rather, Puno expresses concern for failure and states that the shock absorber feature "decrease[s] the chance of failure of the screw or the bone-screw interface" because "it prevent[s] direct transfer of load from the rod to the bone-screw interface." Puno col.3 ll.64-67 (emphasis added).

The district court found that the addition of Anderson's compression member to Puno's device would have eliminated or reduced the device's desired "shock absorber" effect, which then "would increase the chance that screw and bone-screw interface failure would occur." *Ensnarement Order,* 526 F.Supp.2d at 172. The causal relationship between rigidity and screw failure described in Puno is supported by the testimony of DePuy's expert, Dr. Erik Karl Antonsson, *see* J.A. 5546-47, 5555 (testifying that rigidity increases the likelihood of "screw breakage" or failure). Medtronic does not specifically challenge that testimony on appeal. Rather, Medtronic's challenge to the conclusion that Puno teaches away from a rigid screw is directed at other teachings in the prior art, which, in Medtronic's view, would have motivated a person of ordinary skill to look past Puno's warning regarding screw failure.

First, Medtronic directs us to an opinion of this court in a different case, in which we construed the word "operatively" in the phrase "lower bone interface operatively joined to said bone segment" in Puno's claim 5 to mean effective to perform "posterior stabilization" of the spine rather than "micro-motion," proffered by Medtronic in that

case to mean " 'limited motion' between the anchor and the bone." *Cross Medical Prods., Inc. v. Medtronic Sofamor Danek, Inc.,* 424 F.3d 1293, 1305 (Fed.Cir.2005). According to Medtronic in the present appeal, our claim construction in *Cross Medical* shows that Puno's screws are not limited to "micro" or "limited" motion and that Puno's screws can therefore be rigid. The district court rejected this argument, noting that it was not clear that "posterior stabilization" and "micro-motion" were mutually exclusive, and regardless of the construction of the claims, that Puno's specification taught away from a rigid screw. *Ensnarement Order,* 526 F.Supp.2d at 172 n. 13. We agree with the district court. Nothing in our construction of the word "operatively" in *Cross Medical* specifies what degree of rigidity is needed between Puno's anchor seat and vertebrae to achieve posterior stabilization, or that Puno's "shock absorber" effect-a stated advantage of the patent-is incompatible with achieving posterior stabilization. The claim construction of the word "operatively" in no way overshadows the specification's warning against increased rigidity.

***1328** Second, Medtronic points to U.S. Patent No. 4,946,458 ("Harms patent"), which lists the same inventors as those on the '678 patent and discloses how certain fasteners may be tightened or loosened "as desired" to achieve either "a substantially stiff connection" or "a desired dampening movement." Harms patent col.5 ll.8-16. The Harms patent is silent, however, as to why a person of ordinary skill would have "desired" either of these rigidity levels, much less why a rigid connection would have been selected in the face of Puno's warning against such rigidity.

Finally, Medtronic submits that a third patent, which lists Dr. Rolando Puno as a co-inventor, teaches a screw-and-rod system with an "intermediate" amount of rigidity. U.S. Patent No. 4,805,602 col.1 ll.58-60 ("Puno '602 patent"). This teaching, in Medtronic's view, would have motivated the creation of a rigid screw. But the Puno '602 patent explains that this "intermediate" amount of rigidity represents a trade-off between the advantages and disadvantages of "wired implant" and "plate systems." *Id.* Whereas "wired implants have the *advantages* of ... *decreasing rigidity,*" *id.* col.2 ll.55-58 (emphases added), "the use of plates with the screws is *more rigid* than the wired implants and ... can cause *dislocation or even shearing* of the screw," *id.* col.2 ll.64-67 (emphases added). The Puno '602 patent consistently views low rigidity as an advantage and high rigidity as a disadvantage, one that should be avoided whenever possible. The Puno '602 patent thus bolsters, rather than undermines, the district court's finding that the prior art teaches away from rigid pedicle screws.

For the foregoing reasons, we conclude that the district court correctly found that Puno, viewed against the backdrop of the collective teachings of the prior art, teaches away from a rigid pedicle screw encompassed by the hypothetical claim, such that a person of ordinary skill would have been deterred from combining Puno and Anderson in the manner that Medtronic proposes.

We also believe that certain secondary considerations-"failure by others" and "copying"-support the view that this combination would not have been obvious at the time of invention. The district court found that when Medtronic set out to design a rigid pedicle screw in 1991-after the '678 patent's 1989 priority date but before it was issued and published in May 1993-Medtronic's engineers initially settled on a design that involved using a rod, not a compression member, to exert pressure on the screw head. *Ensnarement Order,* 526 F.Supp.2d at 174-75. Medtronic's engineers were focused on solving the same problem as the '678 patent-making Puno's device more rigid-and were also aware of compression members analogous to those found in Anderson. *Id.* at 174; J.A. 5532. As late as April 1993, Dr. Kevin Foley, a member of the Medtronic team that had been working to develop a rigid pedicle screw, considered their alternate design (with no compression member) to be the "best solution"

for making Puno's device more rigid.[FN1] J.A. 5534. When the ' 678 patent issued the following month, however, Medtronic's team suddenly changed direction and decided to insert a compression member between the rod and the screw head, in the manner disclosed in the '678 patent. *Id.* This new design eventually became what is now the accused Vertex® model. The district court inferred from these facts that Medtronic relied on and copied the patent's "compression member" limitation. *Ensnarement Order,* 526 F.Supp.2d at 175. ***1329** On appeal, Medtronic argues that it did not copy the patent but tried, albeit unsuccessfully, to design around the patent's "spherically-shaped" limitation to avoid infringement. But Medtronic does not allege that it independently conceived the idea of adding a compression member to a pedicle screw; indeed, Medtronic does not specifically deny copying the patent's "compression member" concept. Because the addition of a compression member to a pedicle screw is what Medtronic argues would have been obvious, we agree with the district court that Medtronic's initial attempt at making a rigid pedicle screw without a compression member, together with Medtronic's prompt adoption of the claimed feature soon after the patent issued, are relevant indicia of nonobviousness. *See Graham,* 383 U.S. at 17-18, 86 S.Ct. 684 (stating that secondary considerations may "give light to the circumstances surrounding the origin of the subject matter sought to be patented").

FN1. The district court found that Dr. Foley is "a person highly skilled in the relevant art," a finding that Medtronic does not dispute. *Ensnarement Order,* 526 F.Supp.2d at 174.

For the foregoing reasons, we hold that the hypothetical claim would not have been obvious in view of Puno and Anderson and, therefore, the district court properly denied Medtronic's ensnarement defense.[FN2]

FN2. We reach this conclusion even assuming, but without deciding, that Puno constitutes prior art and that Anderson is analogous.

II. Lost Profits

[21][22] Medtronic challenges the jury's award of $149.1 million in lost profits on patented pedicle screws and $77.2 million in lost profits on unpatented, so-called "pull-through" products. We review the district court's denial of Medtronic's motion for JMOL under the law of the regional circuit in which an appeal from the district court would usually lie. *Summit Tech., Inc. v. Nidek Co.,* 363 F.3d 1219, 1223 (Fed.Cir.2004). In the First Circuit, "[t]he district court's decision to grant or deny a motion for judgment as a matter of law is reviewed de novo." *Soto-Lebron v. Fed. Express Corp.,* 538 F.3d 45, 56 (1st Cir.2008). JMOL is warranted when "the presentation of the party's case reveals 'no legally sufficient evidentiary basis' for a reasonable jury to find for that party." *Mag Jewelry Co. v. Cherokee, Inc.,* 496 F.3d 108, 117 (1st Cir.2007) (quoting Fed.R.Civ.P. 50(a)(1)).

A. Pedicle Screws

[23] At trial, DePuy argued that Medtronic's infringing sales of Vertex® pedicle screws caused DePuy to lose $149.1 million in profits that DePuy would have made by selling its own pedicle screw system, marketed as Summit™ and Mountaineer™. DePuy advanced a lost-profits theory under the four-factor *Panduit* test, which requires a showing of (1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) manufacturing and marketing capability to exploit the demand, and (4) the amount of profit that would have been made. *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.,* 575 F.2d 1152, 1156 (6th Cir.1978). The district court instructed the jury on each of these four factors, and the jury found in favor of DePuy. On appeal, Medtronic challenges the sufficiency of the first two *Panduit* factors.

1. Demand for the Patented Product

[24] Medtronic argues that the verdict cannot be upheld because DePuy failed to show, under the first *Panduit* factor, that the demand for DePuy's Summit™ and Mountaineer™ pedicle screws was driven by the screws' "top-loading" feature. It is this top-loading feature, in Medtronic's view, that distinguishes DePuy's patented screws and Medtronic's infringing Vertex® ***1330** screws from Medtronic's bottom-loading screws, which do not infringe the '678 patent and which are not at issue in the present appeal. See *DePuy Spine I,* 469 F.3d at 1022 (holding that Medtronic's bottom-loading screws, unlike its top-loading Vertex® screws, do not possess claim 1's "opening" limitation). Accordingly, Medtronic asks us to hold that the requisite demand under the first *Panduit* factor is demand for the specific feature (i.e., claim limitation) that distinguishes the patented product from a noninfringing substitute, not simply demand for the patented product.

We decline Medtronic's request. Medtronic's argument unnecessarily conflates the first and second *Panduit* factors. All that the first factor states, and thus requires, is "demand for the patented product." *Panduit,* 575 F.2d at 1156. This factor does not require any allocation of consumer demand among the various limitations recited in a patent claim. Instead, the first *Panduit* factor simply asks whether demand existed for the "patented product," i.e., a product that is "covered by the patent in suit" or that "directly competes with the infringing device." *Rite-Hite Corp. v. Kelley Co.,* 56 F.3d 1538, 1548-49 (Fed.Cir.1995) (en banc).

In this case, Medtronic does not dispute that demand generally existed for the Summit™ and Mountaineer™ pedicle screws and that those screws are covered by the '678 patent. Medtronic also concedes that demand for those screws was driven primarily by their polyaxial capability, a feature inherent in both Medtronic's accused Vertex® screws and DePuy's Summit™ and Mountaineer™ screws. Because the jury heard testimony as to this fact, an evidentiary basis was thus presented from which the jury could have found "demand for the patented product" under the first *Panduit* factor.

Medtronic argues that our prior decisions in *Grain Processing, Slimfold,* and *Ferguson* compel a different result. We disagree. In *Grain Processing,* the district court found that certain claim limitations could easily be omitted from the accused product in a manner that was perfectly acceptable to consumers. In particular, the court found that there was no specific demand for the features corresponding to the omitted claim limitations and that an acceptable noninfringing substitute was readily available. *Grain Processing Corp. v. Am. Maize-Products Co.,* 979 F.Supp. 1233, 1237 (N.D.Ind.1997) (Easterbrook, J.), aff'd, 185 F.3d 1341 (Fed.Cir.1999). On appeal, we affirmed the denial of lost profits, not because demand was absent under the first *Panduit* factor, but because acceptable noninfringing substitutes were available under the second *Panduit* factor. 185 F.3d at 1354-55 (holding that a noninfringing substitute was both "available" and "acceptable" during the accounting period, thus failing *Panduit*'s second factor).

Like our decision in *Grain Processing,* our decision in *Slimfold* affirmed a denial of lost profits, not because demand was lacking under the first *Panduit* factor, but because acceptable noninfringing substitutes were available under the second. *Slimfold Mfg. Co., Inc. v. Kinkead Indus., Inc.,* 932 F.2d 1453, 1458 (Fed.Cir.1991). In that case, "[w]ith respect to the availability of acceptable non-infringing substitutes"-i.e., the second *Panduit* factor-the district court found that certain "old hardware," previously used by the accused infringer, did not infringe the patent-in-suit and was both available and acceptable to consumers. *Id.* On appeal, the patentee argued that the old hardware was not "acceptable" to customers because it lacked features corresponding to claim limitations that were supposed "advantages" of the patented product. *Id.* We rejected that argument because the evidence showed ***1331** that the supposed "advantages" of

the patented product were not at all important to consumers, thus indicating that the old hardware was an *acceptable* noninfringing substitute under the second *Panduit* factor.

Medtronic's reliance on *Ferguson* fares no better. *Ferguson* dealt with lost profits under the "entire market value" rule, which permits a patentee to recover the entire value of an apparatus that contains both patented and unpatented components, so long as the patented component is the basis for customer demand. *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC,* 350 F.3d 1327, 1346 (Fed.Cir.2003) (vacating and remanding lost profits award for entire value of a device containing a first component embodying a first patent, found infringed, as well as a second component embodying a second patent, found not infringed, where profits could fairly be allocated to customer demand for second component); see *Rite-Hite,* 56 F.3d at 1549 ("[T]he entire market value rule permits recovery of damages based on the value of a patentee's entire apparatus containing several features when the patent-related feature is the 'basis for customer demand.' ") (quoting *State Indus., Inc. v. MorFlo Indus., Inc.,* 883 F.2d 1573, 1580 (Fed.Cir.1989)). In the present case, Medtronic challenges the lost-profits award for Summit™ and Mountaineer™ pedicle screws under the *Panduit* factors, not under the "entire market value" rule. *Ferguson* is also factually distinguishable. As previously noted, the polyaxial capability of the patented pedicle screws-the capability that Medtronic admits drove sales of Summit™ and Mountaineer™ pedicle screws-is itself an inherent feature of the patented screws, not a feature of some other, unpatented device that may also be used in the surgery.

[25] As we have held, the focus on particular features corresponding to individual claim limitations is unnecessary when considering whether demand exists for a patented product under the first *Panduit* factor. Rather, the elimination or substitution of particular features corresponding to one or more claim limitations goes to the availability of acceptable noninfringing substitutes under the second *Panduit* factor, to which we now turn.

2. Noninfringing Substitutes

Medtronic asserts that DePuy failed to establish the second *Panduit* factor because it contends that noninfringing, bottom-loading pedicle screws were available during the relevant accounting period (2000-2003).[FN3] However, because Medtronic did not actually have a noninfringing substitute "on the market" during the relevant accounting period, it was Medtronic that bore the burden of overcoming the inference of unavailability. *Grain Processing,* 185 F.3d at 1353 ("When an alleged alternative is not on the market during the accounting period, a trial court may reasonably infer that it was not available as a noninfringing substitute at that time."). Medtronic had to show that the substitute was "available" during this period based on alternative actions that Medtronic reasonably could have taken to avoid infringement. *Id.* In this regard, Medtronic asserts that it could have made a noninfringing, bottom-loading version of Vertex® screws in 2000-2003 and that it did in fact provide such screws for use in a surgery in 2007. Alternatively, Medtronic ***1332** argues that it was unfairly precluded from introducing into evidence the district court's 2004 summary judgment ruling that the top-loading Vertex® model did not infringe the '678 patent. Medtronic believes that this evidence would have helped the jury to understand why Medtronic did not switch to a noninfringing, bottom-loading design until 2007. We address these arguments in turn.

> FN3. DePuy admits that in "late 2003, acceptable noninfringing alternatives from third parties became available" and states that its expert accounted for these alternatives using a market-share analysis. DePuy's Principal Br. at 42. Medtronic does not specifically contest the market-share analysis but challenges the availabil-

ity of lost profits generally.

[26] First, substantial evidence supports the jury's factual finding under the second *Panduit* factor that no acceptable noninfringing alternative was available between 2000 and 2003. DePuy presented evidence of Medtronic's three unsuccessful attempts (in 2000, 2003-2004, and 2006-2007) to develop a noninfringing, bottom-loading design. For example, the jury heard testimony that Medtronic's various bottom-loading prototypes were deemed "too large" by surgeons, were "substantially weaker" in pull-out strength than the infringing, top-loading Vertex® model, and had never been submitted to the Food & Drug Administration for the necessary marketing approval. J.A. 5214. Based on this evidence, a reasonable jury could have concluded, as it apparently did, that even if Medtronic had pursued a bottom-loading design rather than the infringing, top-loading Vertex® model, the bottom-loading design would not have been available or acceptable to consumers before the end of 2003.

[27] Second, we discern no abuse of discretion in the district court's exclusion of its 2004 summary judgment ruling that the top-loading Vertex® model did not infringe, which we reversed in 2006 as to equivalents, and which Medtronic contends is the reason why it did not switch to a bottom-loading design until 2007. *See Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1267 (Fed.Cir.2008) (applying First Circuit's abuse of discretion standard to review of evidentiary rulings) (citing *Cavallaro v. United States*, 284 F.3d 236, 245 (1st Cir.2002)). In excluding this evidence, the district court stated that the relevance of its prior ruling was "almost insignificant" in view of the "plethora of evidence that's gone in" and that the substance of the ruling was "erroneous" in view of our subsequent reversal. J.A. 5253. We agree that the probative value of this evidence was low compared to the risk of jury confusion. Although the district court's favorable 2004 ruling might have been the reason that Medtronic felt content to wait until after our 2006 decision to actually develop a noninfringing, bottom-loading version of Vertex®, the theory of available substitutes that Medtronic pressed at trial assumed a hypothetical "but-for world" in which Medtronic focused exclusively on developing a bottom-loading design. In this "but-for world," a legal ruling in 2004 would have had little bearing on the technical feasibility of Medtronic's redesign efforts in the critical timeframe of 2000-2003. The summary judgment ruling would not have addressed why Medtronic had failed three times prior to 2007 to overcome the various technical and regulatory hurdles in achieving a noninfringing design. If the district court had admitted the 2004 ruling into evidence, however, it would have had to explain to the jury that the court had previously decided the infringement issue, that the decision was overruled in part with regard to equivalence but not literal infringement, and that the jury must ignore this evidence when deciding equivalence for itself but may later consider it when assessing damages. The risk of jury confusion is apparent. The decision to exclude this evidence was not an abuse of discretion.

For the foregoing reasons, we affirm the award of lost-profits damages as to the patented pedicle screws.

***1333** B. "Pull-Through" Products

The jury also awarded DePuy $77.2 million in profits that DePuy believes it would have made from selling so-called "pull-through" products but that were purportedly lost when Medtronic sold its infringing Vertex® pedicle screws. DePuy's damages expert could not identify specifically what products he included in his lost-profits analysis, but speculated that pull-through products included such things as head braces, vests, and other products not used in spinal surgeries. J.A. 5246. He admitted that these products are not covered by the '678 patent, do not compete with the patented pedicle screws, have no functional relationship with the patented pedicle screws, and can be used independently of the patented pedicle screws. *Id.* Instead,

these products are related only by virtue of the business relationship that is created when a customer first buys a patented Summit™ or Mountaineer™ device. *Id.* at 5235 ("The advanced product serves as ... a door-opener. It gets you in. It gets you working with the surgeon, subsequently you have the opportunity to makes sales that you might not otherwise have made."). It is this business relationship that gave rise to DePuy's characterization of these products as "pull-through" products. Medtronic argues that these lost-profit damages are foreclosed by our decisions in *Rite-Hite Corp. v. Kelley Co.,* 56 F.3d 1538 (Fed.Cir.1995) (en banc), and *American Seating Co. v. USSC Group,* 514 F.3d 1262 (Fed.Cir.2008).

[28][29][30][31] "Whether lost profits are legally compensable in a particular situation is a question of law that we review *de novo*." *Poly-Am., L.P. v. GSE Lining Tech., Inc.,* 383 F.3d 1303, 1311 (Fed.Cir.2004) (citing *Rite-Hite,* 56 F.3d at 1544). "A patentee may recover lost profits on unpatented components sold with a patented item, a convoyed sale, if both the patented and unpatented products 'together were considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit.' " *Am. Seating,* 514 F.3d at 1268 (quoting *Rite-Hite,* 56 F.3d at 1550). In contrast to such functionally-integrated components that are properly subject to lost profits, "there is no basis for extending that recovery to include damages for [unpatented] items that are neither competitive with nor function with the patented invention." *Rite-Hite,* F.3d at 1551. For example, lost profits cannot be recovered on unpatented items "that have essentially no functional relationship to the patented invention and that may have been sold with an infringing device only as a matter of convenience or business advantage." *Id.* at 1550. Because it is undisputed that DePuy's unpatented pull-through products neither compete nor function with its patented Summit™ and Mountaineer™ devices and were sold (i.e., "pulled-through") only by virtue of DePuy's business relationship with surgeons, DePuy was not legally entitled to recover lost profits on those unpatented products.

DePuy attempts to distinguish *Rite-Hite* and *American Seating* on the ground that those cases dealt with "convoyed sales," in which the patented and unpatented products were sold together, whereas DePuy's pull-through products are sold in separate transactions following the initial sale of its patented Summit™ and Mountaineer™ devices. This is a distinction without a difference. To hold otherwise would be to allow a patentee to circumvent *Rite-Hite* and *American Seating* by simply executing separate sales contracts. Like DePuy's pull-through products, the unpatented dock levelers in *Rite-Hite* were sold with the patented vehicle restraints "only for marketing reasons, not because they essentially functioned together." 56 F.3d at 1551. Similarly, in *American Seating,* the patented tie-down system ***1334** and unpatented passenger seats were sold together "for reasons of convenience and 'one-stop shopping,' not because of an absolute requirement that the two items function together." 514 F.3d at 1269. Because "the *Rite-Hite* 'functional unit' test set[s] forth the key criterion for lost profits of unpatented materials" that are sold with (or sold separately as a result of) a patented item, the jury had no legal basis to award lost profits on DePuy's unpatented pull-through products, which neither compete nor function with its patented pedicle screws. *Juicy Whip, Inc. v. Orange Bang, Inc.,* 382 F.3d 1367, 1372 (Fed.Cir.2004).

Accordingly, we reverse the award of lost-profit damages on pull-through products.

III. Royalty Damages

[32] On cross-appeal, DePuy challenges the district court's denial of a motion for new trial on the issue of reasonable-royalty damages. At trial, DePuy argued for a 15% royalty rate on $237.2 million worth of infringing sales that were not subject to DePuy's claim for lost profits, for a total of $31.8 million in royalties. Medtronic disputed this royalty rate and argued instead that a 6% rate would give

DePuy "full and fair compensation" if its products were found to infringe. J.A. 5473. DePuy therefore believes that the jury should have simply picked a number between 6% and 15%. The jury awarded 0%. Shortly after the jury was dismissed, DePuy indicated to the court that the jury "may have possibly misunderstood" that the reasonable royalty applied to a different set of infringing sales, but ultimately told the court that DePuy "will be investigating" the issue and "[m]aybe we will conclude that there is nothing." J.A. 5501-02. Several weeks later, DePuy filed a motion for new trial on royalty damages.

[33][34] "We review decisions on ... motions for a new trial under the law of the regional circuit." *Lucent Tech., Inc. v. Gateway, Inc.*, 543 F.3d 710, 717 (Fed.Cir.2008). The First Circuit reviews the denial of a motion for new trial for an abuse of discretion. *Davignon v. Hodgson*, 524 F.3d 91, 100 (1st Cir.2008). Here, the district court cited the First Circuit's *Wennik* decision, which sets forth the circuit's "iron-clad rule that a party 'waives [the issue of] inconsistency if it fails to object after the verdict is read and before the jury is dismissed.' " *Wennik v. Polygram Group Distrib., Inc.*, 304 F.3d 123, 130 (1st Cir.2002) (alteration in original) (quoting *Toucet v. Mar. Overseas Corp.*, 991 F.2d 5, 8 (1st Cir.1993)). Under this precedent, the district court stated that it was unclear why the jury awarded a 0% royalty rate in light of "other aspects of the jury's verdict," but that any inconsistency in the verdict should have been resolved before the jury was discharged. *Feb. 14 Order* at 1. For that reason, the district court denied DePuy's motion.

DePuy resists characterizing the jury's award of a 0% royalty rate as an "inconsistency," arguing instead that the award lacks evidentiary support. We disagree and fail to see this as a question of evidence. The jury verdict, on its face, was inconsistent. A 0% royalty rate cannot be squared with: (1) the jury's finding that the subject sales constituted acts of infringement, and (2) the instruction that the jury choose a royalty rate between 6% and 15%-the sole form of compensation that DePuy requested on those sales. As the district court correctly observed, these "other aspects of the jury's verdict" should have resulted in a royalty rate between 6% and 15%. We therefore agree with the district court that the award of 0% rendered the verdict inconsistent.

***1335** The jury may well have been confused by the wording used in the special verdict form, which expressly instructs the jury to "answer Question Nos. 11 and 12" (calculation of royalty rate) if they found that DePuy is *not* entitled to lost profits, but to "answer Question No. 10" (calculation of lost profits) if they found that DePuy *is* entitled to lost profits. J.A. 9. In the latter event, if lost profits are available (as the jury found here), the form says nothing about answering Question Nos. 11 and 12 regarding the royalty rate. Those questions themselves ask for a royalty on "an infringement for which plaintiffs are *not* entitled to recover lost profits," without specifying which "infringement" or sale was at issue. *Id.* (emphasis added). [FN4] Whatever the cause, the verdict was inconsistent, placing an obligation on DePuy to object. In view of the First Circuit's "iron-clad rule" barring untimely inconsistency objections, and given DePuy's awareness of the issue and its ability to have properly objected, we cannot say that the denial of DePuy's motion for new trial was an abuse of discretion.

> FN4. A general instruction to answer all of Question Nos. 9, 10, 11 and 12 is found on the preceding page of the verdict form, J.A. 8, but is superseded on the next page by what appears to be more specific instructions, discussed *supra*.

Moreover, we need not decide in this case whether an otherwise untimely inconsistency objection can ever be saved by the statutory damages floor of 35 U.S.C. § 284 (setting a damages floor not "less than a reasonable royalty for the use made of the invention by the infringer"). DePuy's $149.1 million lost-profits award, which we have affirmed, *exceeds* DePuy's alternative request for $59.2 million in

total damages based solely on royalties on all of Medtronic's accused sales-i.e., the entire "use made of the invention by the infringer" under § 284. J.A. 5520-21, 12263 (requesting, in the alternative if lost profits were found unavailable, $59.2 million in royalties on all $462 million in accused sales).

Accordingly, the denial of DePuy's motion for new trial is affirmed.

IV. Willfulness

The jury found that Medtronic's Vertex® model infringed the '678 patent under the doctrine of equivalents. DePuy argued that this infringement was willful. At the close of evidence, however, the district court granted Medtronic's motion for JMOL of no willfulness, applying the willfulness standard articulated in *In re Seagate Technology, LLC,* 497 F.3d 1360, 1371 (Fed.Cir.2007) (en banc). On cross-appeal, DePuy argues that the evidence was sufficient for willfulness to have gone to the jury.

We review the grant of JMOL under the law of the regional circuit. See *Proveris Scientific,* 536 F.3d at 1266. The First Circuit applies a de novo standard of review. *See Soto-Lebron,* 538 F.3d at 56. JMOL is appropriate when "a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed.R.Civ.P. 50(a)(1). In *Seagate,* we held that "to establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent.... If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." 497 F.3d at 1371.

***1336** As to *Seagate*'s first prong, DePuy argues that the jury could have concluded, as the district court later did at the ensnarement hearing, that Medtronic "copied" the invention directly out of the '678 patent. According to DePuy, "knowingly copying a competitor's patented invention is objectively risky behavior of the highest order." DePuy's Principal Br. at 70. Medtronic counters that DePuy's allegation of "knowingly copying" bears only on Medtronic's state of mind, which is not relevant to the objective inquiry under *Seagate*'s first prong. Rather, the objective reasonableness of its conduct is confirmed, in Medtronic's view, by the result of the prior appeal in *DePuy I,* in which we affirmed the grant of summary judgment of no literal infringement and remanded for a jury to resolve infringement under the doctrine of equivalents.

[35][36][37] We agree with Medtronic and the district court that there was no legally sufficient evidentiary basis to find an objectively high likelihood under *Seagate*'s first prong that the Vertex® model (which contains a conically-shaped portion) infringed the '678 patent (whose claims recite a "spherically-shaped portion"). *Seagate*'s first prong is objective, and "[t]he state of mind of the accused infringer is not relevant to this objective inquiry." *Seagate,* 497 F.3d at 1371. Similarly, evidence of copying is "of no import on the question of whether the claims of an issued patent are infringed," either literally or by equivalents. *Allen Eng'g Corp. v. Bartell Indus., Inc.,* 299 F.3d 1336, 1351 (Fed.Cir.2002) (citing *Warner-Jenkinson,* 520 U.S. at 35-36, 117 S.Ct. 1040). Accordingly, evidence of copying in a case of direct infringement is relevant only to *Seagate*'s second prong, as it may show what the accused infringer knew or should have known about the likelihood of its infringement.

In the prior appeal, we affirmed the district court's grant of summary judgment of no literal infringement, concluding that no reasonable jury could have found that the Vertex® model's conically-shaped portion literally meets the claimed "spherically-shaped" limitation. *DePuy I,* 469 F.3d at 1016. Moreover, in reversing the district court's grant of summary judgment of noninfringement un-

der the doctrine of equivalents, we held that a question of material fact exists as to whether the difference between the two shapes is substantial. *Id.* at 1020. A jury was needed to resolve that question on remand. At the close of evidence at trial, the district court denied DePuy's motion for JMOL of infringement under the doctrine of equivalents.

Medtronic presented a substantial question of non-infringement under the doctrine of equivalents. The specification of the '678 patent explains that the screw head achieves a "rigid lock" when it is "*completely* surrounded" by the spherically-shaped surface of a receiver member whose radius of curvature is equal to that of the screw head. '678 patent col.2 ll.21-53, col.3 l.56-col.4 l.7 (emphasis added). By contrast, the screw head is only *partially* surrounded, along a circle in one plane, when a conical shape is used in the inner hollow space of the receiver member. This evidence tends to show a lack of equivalence, because it shows that a conical surface achieves a rigid lock in a different "way" than a spherical surface. *See Warner-Jenkinson,* 520 U.S. at 39, 117 S.Ct. 1040 (acknowledging that there is "substantial agreement" that the function-way-result test for equivalence is particularly "suitable for analyzing mechanical devices"). On the other hand, DePuy submitted evidence tending to show that conical and spherical surfaces are interchangeable. But even accepting DePuy's view of the facts that conical and spherical surfaces***1337** are interchangeable, a finding of equivalence does not necessarily follow. *See Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.,* 145 F.3d 1303, 1309 (Fed.Cir.1998) ("[A] finding of known interchangeability, while an important factor in determining equivalence, is certainly *not dispositive.* ") (emphasis added). The jury could have reasonably found for either party on the question of equivalence. While the fact that an issue was submitted to a jury does not automatically immunize an accused infringer from a finding of willful infringement, the record developed in the infringement proceeding in this case, viewed objectively, indisputably shows that the question of equivalence was a close one, particularly insofar as equivalence "requires an intensely factual inquiry." *Vehicular Tech. Corp. v. Titan Wheel Int'l, Inc.,* 212 F.3d 1377, 1381 (Fed.Cir.2000). The mere fact that the jury ultimately found equivalence does not diminish the difficulty of their task, which must be viewed objectively. Accordingly, the district court was correct to rule on JMOL that an objectively high likelihood of infringement could not have been found under *Seagate*'s first prong.

Because we hold that DePuy failed as a matter of law to satisfy *Seagate*'s first prong, we need not address DePuy's arguments concerning "copying" and Medtronic's rebuttal evidence concerning "designing around," both of which are relevant only to Medtronic's mental state regarding its direct infringement under *Seagate*'s second prong. Moreover, because "an award of enhanced damages requires a showing of willful infringement," *Seagate,* 497 F.3d at 1368 (citing *Beatrice Foods Co. v. New England Printing & Lithographing Co.,* 923 F.2d 1576, 1578 (Fed.Cir.1991)), DePuy is not entitled to enhanced damages. See *Cohesive Tech., Inc. v. Waters Corp.,* 543 F.3d 1351, 1374 (Fed.Cir.2008) ("The majority of the en banc court in *Seagate* did not elect to overrule *Beatrice Foods,* and we therefore remain bound by that decision.").

Accordingly, we affirm the grant of JMOL of no willfulness.

V. Attorney Fees and Sanction

Medtronic challenges the district court's imposition of $425,375 in attorney fees under 35 U.S.C. § 285 and a further $10 million sanction under the court's inherent authority, based on what the court perceived to be Medtronic's litigation misconduct.

[38][39] "Where a district court finds a case exceptional under 35 U.S.C. § 285, this court reviews the underlying factual findings for clear error and legal conclusions without deference. Once the district court has found a case to be exceptional, we review

any award of attorney fees for an abuse of discretion." *Frazier v. Roessel Cine Photo Tech, Inc.,* 417 F.3d 1230, 1234 (Fed.Cir.2005) (citing *Rambus Inc. v. Infineon Tech. Ag,* 318 F.3d 1081, 1088 (Fed.Cir.2003)). "A court's exercise of its inherent powers is reviewed for an abuse of discretion." *Pickholtz v. Rainbow Tech., Inc.,* 284 F.3d 1365, 1376 (Fed.Cir.2002).

The district court found that Medtronic "fail[ed] to accept the claim construction governing this case" and that its infringement defense appeared to have been "wholly based on an attempt to obscure, evade, or minimize the Federal Circuit's construction of the patent-in-suit." *Sanctions Order,* 534 F.Supp.2d at 225. Specifically, in the prior appeal, we construed the term "pressed against the hollow spherically-shaped portion" to be literally met whenever the screw head "presses against all or any part of that portion-including the edge." *DePuy I,* 469 F.3d at 1015. At trial, Medtronic did not dispute that the accused Vertex® model literally meets this limitation, given that the screw ***1338** head "presses against ... the edge" of the conically-shaped portion. Instead, Medtronic attempted to invoke the so-called "reverse doctrine of equivalents" as an infringement defense against this particular claim limitation, arguing that a screw head presses against a conically-shaped portion in a "substantially different way" than it does against a spherically-shaped portion-via an "interference fit" rather than a "mating fit." J.A. 5334-35.

We have explained that "[t]he reverse doctrine of equivalents is an equitable doctrine designed 'to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention.' " *Roche Palo Alto LLC v. Apotex, Inc.,* 531 F.3d 1372, 1377 (Fed.Cir.2008) (quoting *Scripps Clinic & Research Found. v. Genentech, Inc.,* 927 F.2d 1565, 1581 (Fed.Cir.1991)). According to the Supreme Court:

> [W]here a device is *so far changed in principle* from a patented article that it performs the same or similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the [reverse] doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement.

Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608-09, 70 S.Ct. 854, 94 L.Ed. 1097 (1950) (emphasis added). Because the reverse doctrine of equivalents requires a fundamental change in the basic principle by which the device operates, the doctrine is rarely invoked and virtually never sustained. *See Roche,* 531 F.3d at 1378 ("[T]his court has never affirmed a finding of non-infringement under the reverse doctrine of equivalents."); *Leesona Corp. v. United States,* 208 Ct.Cl. 871, 530 F.2d 896, 906 (1976) (predecessor court finding no infringement despite the fact that the accused structure, "*in a very loose sense,*" could be said to fall within the literal words of the claim (emphasis added)).

In this case, the district court faulted Medtronic and its experts for arguing that the "pressed against" limitation of the patented device operates using "mating surfaces between the screw head and the receiver member, which ... renders it substantially different from the accused products (which have non-mating surfaces that lock the screw by means of an interference fit)." *Sanctions Order,* 534 F.Supp.2d at 225-26. In the district court's view, Medtronic's argument "flouted the governing claim construction as set forth by the Federal Circuit" and "threatened to mislead and confuse the jury." *Id.* at 226, 227.

[40] The basis for the district court's conclusion that Medtronic's argument "flouted the governing claim construction" is revealed in a separate post-trial order, issued several weeks before the sanctions order. In the earlier order, the district court stated that "the [reverse] doctrine [of equivalents] (which requires literal infringement) does not apply to the accused Vertex devices themselves because they do not literally infringe the ' 678 patent," emphasizing the fact that the case had been remanded by the Federal Circuit for a determination of in-

fringement under the doctrine of equivalents only. *Feb. 6 Order,* 533 F.Supp.2d at 245-46 ("[T]he reverse doctrine of equivalents was simply inapplicable in this case and served only to confuse the jury."). However, the district court's understanding of the circumstances in which the reverse doctrine of equivalents may be asserted is incorrect. The reverse doctrine of equivalents, like the doctrine of equivalents, is applied to individual limitations of a claim. *See Warner-Jenkinson,* 520 U.S. at 29, 117 S.Ct. 1040 ("[T]he doctrine of equivalents must be applied to individual elements of the claim, ***1339** not to the invention as a whole."); *Leesona,* 530 F.2d at 906 (applying reverse doctrine of equivalents to "porous self-sustaining metal layer" limitation). Thus, the fact that DePuy argued the "spherically-shaped portion" limitation under a doctrine of equivalents theory of infringement did not prevent Medtronic from raising the reverse doctrine of equivalents against the *literal* scope of a different limitation, namely, the "pressed against" limitation.

As for the argument that the reverse doctrine of equivalents "threatened to mislead and confuse the jury," the unusual nature of the reverse doctrine of equivalents is not itself a reason to sanction a party for invoking it. The Supreme Court has recognized it to be a viable defense, even if it is rarely asserted.

[41] Apart from Medtronic's mere assertion of the reverse doctrine of equivalents, there was no finding in this case that Medtronic litigated the defense in bad faith. Although the district court ultimately concluded that the underlying substance of Medtronic's defense "lacks merit," *Sanctions Order,* 534 F.Supp.2d at 226, there is no indication, much less a finding, that Medtronic's arguments were baseless, frivolous, or intended primarily to mislead the jury. Although the defense ultimately failed, Medtronic should not have been sanctioned for merely raising it, absent a finding of "vexatious or unjustified litigation," "frivolous suit," or other type of "bad faith." *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.,* 549 F.3d 1381, 1387 (Fed.Cir.2008); *see Beckman Instruments, Inc. v. LKB Produkter AB,* 892 F.2d 1547, 1552 (Fed.Cir.1989) (stating that a purpose of 35 U.S.C. § 285 is to prevent " 'gross injustice' when the accused infringer has litigated in bad faith").

[42] Because the district court's exceptionality finding was based on Medtronic's mere assertion of the reverse doctrine of equivalents, rather than the way in which Medtronic litigated it, the finding of exceptionality in this case was erroneous. The district court's imposition of $425,375 in attorney fees is, therefore, reversed. We also reverse the court's *sua sponte* imposition under its inherent authority of a $10 million sanction, which was premised on the same alleged misconduct and cannot be sustained.

VI. Post-Judgment Interest

In this appeal, we have reduced the amount of the district court's damages award by reversing the lost-profits award on pull-through products while affirming the lost-profits award on pedicle screws. Our decision therefore "modifies" the district court's judgment within the meaning of Federal Rule of Appellate Procedure 37(b), which, in turn, requires us, the appellate tribunal, to specify the allowance of post-judgment interest. *See Mars, Inc. v. Coin Acceptors, Inc.,* 557 F.3d 1377, 1379 (Fed.Cir.2009); *Tronzo v. Biomet, Inc.,* 318 F.3d 1378, 1381 (Fed.Cir.2003) ("[T]he responsibility and authority for [determining whether a party to an appeal is entitled to post-judgment interest] is assigned to the appellate tribunal.").

[43] "The application of Rule 37 is not unique to judgments in patent cases, and thus we look to the law of the regional circuit for guidance." *Tronzo,* 318 F.3d at 1381. In the First Circuit, post-judgment interest accrues from "the initial entry of the district court's judgment on the jury verdict," not from the denial of post-judgment motions. *Marshall v. Perez-Arzuaga,* 866 F.2d 521, 522 (1st Cir.1989). Accordingly, we hold that DePuy is entitled to post-judgment interest at the applicable

statutory rate under 28 U.S.C. § 1961 running from December 11, 2007-the date the district court denied Medtronic's ensnarement defense and entered judgment on the jury verdict. We remand for calculation*1340 of post-judgment interest consistent with this opinion.

CONCLUSION

We affirm the award of $149.1 million in lost profits on patented pedicle screws. We reverse the award of $77.2 million in lost profits on unpatented pull-through products. We also reverse the imposition of $425,375 in attorney fees and the $10 million sanction. We remand for calculation of post-judgment interest at the applicable statutory rate under 28 U.S.C. § 1961 running from December 11, 2007.

AFFIRMED-IN-PART, REVERSED-IN-PART, and *REMANDED*

COSTS

Each party shall bear its own costs.

C.A.Fed. (Mass.),2009.
DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.
567 F.3d 1314, 90 U.S.P.Q.2d 1865

END OF DOCUMENT